

# EXHIBIT B

Jaime Sepulveda, M.D.

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CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A	)	IN THE DISTRICT COURT
JENNIFER GALINDO,	)	
	)	
Plaintiff,	)	
	)	438th JUDICIAL DISTRICT
v.	)	
	)	
CESAR REYES, M.D., JOHNSON &	)	
JOHNSON, AND ETHICON, INC.,	)	BEXAR COUNTY, TEXAS
	)	
Defendants.	)	
	)	

DEPOSITION OF

JAIME SEPULVEDA, M.D.

DATE: April 8, 2016

TIME: 9:17 a.m. - 5:10 p.m.

GOLKOW TECHNOLOGIES, INC.  
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	The deposition of JAIME SEPULVEDA, M.D., a witness in the above-entitled and numbered cause, was taken before me, Dorothy Linda Minor, Registered Professional Reporter and Notary Public for the State of Florida at Large, at 200 South Biscayne Boulevard, Suite 4600, in the City of Miami, County of Miami-Dade, State of Florida, on Friday, the 8th day of April, 2016.	
	APPEARING ON BEHALF OF THE PLAINTIFF:	
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<p>1 APPEARANCES (Continued):</p> <p>2 APPEARING ON BEHALF OF DR. REYES:</p> <p>3 David J. McTaggart, Esq.</p> <p>4 SCOTT, CLAWATER &amp; HOUSTON, LLP</p> <p>5 2727 Allen Parkway, 7th Floor</p> <p>6 Houston, Texas 77019</p> <p>7 dmctaggart@schlawyers.com</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 cause?</p> <p>2 MS. GALLAGHER: Yes, I do, because under</p> <p>3 the rule it says that notice must be given that</p> <p>4 the deposition will be recorded by other than</p> <p>5 stenographic means. It does not say used.</p> <p>6 MR. GOSS: And you refuse to let us go</p> <p>7 forward in the event that we want to record it,</p> <p>8 video it for our own purposes and for no</p> <p>9 purpose to be used at trial?</p> <p>10 MS. GALLAGHER: Yes.</p> <p>11 MR. GOSS: And we've offered you that we</p> <p>12 would not use it for any purpose at trial and</p> <p>13 you refuse to proceed forward, even under that</p> <p>14 condition?</p> <p>15 MS. GALLAGHER: Yes.</p> <p>16 MR. GOSS: Okay. Just for the record, we</p> <p>17 will take this to the Court. In the event that</p> <p>18 the Court determines that we are entitled to</p> <p>19 video it for our own purposes, then we're going</p> <p>20 to ask to come down here and take it again.</p> <p>21 That's all.</p> <p>22 THE VIDEOGRAPHER: This is the end of</p> <p>23 video portion. It's 9:14 a.m.</p> <p>24 THE COURT REPORTER: Raise your right</p> <p>25 hand, please, sir. Do you swear or affirm that</p>
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<p>1 THE VIDEOGRAPHER: We're on the record.</p> <p>2 The witness is not present. Counsel Tim Goss</p> <p>3 has requested the video be turned on for</p> <p>4 objections regarding the video. The time is</p> <p>5 9:12 a.m., and the matter is Jennifer Ramirez</p> <p>6 versus Ethicon, et al. Today's date is April</p> <p>7 8, 2016.</p> <p>8 MS. GALLAGHER: This is Kat Gallagher on</p> <p>9 behalf of Johnson &amp; Johnson, and we have a, and</p> <p>10 Ethicon, and we have a deposition notice for</p> <p>11 Dr. Sepulveda today that was noticed for</p> <p>12 stenographic only. Pursuant to Rule 199.2, we</p> <p>13 object to this going forward by video because</p> <p>14 under Rule 199.2, at least five days prior to</p> <p>15 the deposition, the party must serve on the</p> <p>16 witness and all parties a notice that the</p> <p>17 deposition will be recorded by other than</p> <p>18 stenographic means. We did not get five days</p> <p>19 notice and I object to it going forward by</p> <p>20 video.</p> <p>21 MR. GOSS: And just so I'm clear on your</p> <p>22 objection, you object to us by recording -- you</p> <p>23 object to our recording of the deposition, even</p> <p>24 in the event that we do not intend to use the</p> <p>25 video of the deposition at any trial in this</p>	<p>1 the testimony you are about to give will be the</p> <p>2 truth, the whole truth and nothing but the</p> <p>3 truth?</p> <p>4 THE WITNESS: I do swear.</p> <p>5 THEREUPON,</p> <p>6 JAIME SEPULVEDA, M.D.,</p> <p>7 having been first duly sworn/affirmed to tell the</p> <p>8 truth, the whole truth and nothing but the truth, was</p> <p>9 examined and testified under oath as follows:</p> <p>10 DIRECT EXAMINATION</p> <p>11 BY MR. FREESE:</p> <p>12 Q. Good morning. Good to see you again.</p> <p>13 I'm going to mark Exhibit 1 to your deposition, which</p> <p>14 is the notice of your deposition.</p> <p>15 (Plaintiff Exhibit No. 1 was marked for</p> <p>16 identification.)</p> <p>17 BY MR. FREESE:</p> <p>18 Q. Have you seen that before, sir?</p> <p>19 A. Yes, sir.</p> <p>20 Q. All right, and you were provided a copy</p> <p>21 of it before the deposition?</p> <p>22 A. Yes.</p> <p>23 Q. And you were requested to bring some</p> <p>24 documents?</p> <p>25 A. Yes.</p>

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<p>1       Q. Okay. And did you do so?</p> <p>2       A. Yes, I did.</p> <p>3       Q. And I'm going to mark Exhibit 2 to your</p> <p>4       deposition, which is Ethicon's response to the</p> <p>5       deposition notice.</p> <p>6              (Plaintiff Exhibit No. 2 was marked for</p> <p>7              identification.)</p> <p>8       BY MR. FREESE:</p> <p>9       Q. Have you seen that before?</p> <p>10      A. I see it for the first time now.</p> <p>11      Q. Me showing you now, that's the first time</p> <p>12      you've seen it?</p> <p>13      A. Yes, sir.</p> <p>14      Q. Okay. You don't know what Ethicon</p> <p>15      objected to producing and what it didn't object to</p> <p>16      producing?</p> <p>17      A. Yeah, I'm aware that they objected to my</p> <p>18      1099s.</p> <p>19      Q. Okay, and other than your 1099s, was</p> <p>20      there anything withheld that we requested to be</p> <p>21      brought, other than the 1099s?</p> <p>22      A. Not that, not that I'm aware.</p> <p>23      Q. Okay. So, everything that you have</p> <p>24      looked at and relied upon is either physically in the</p> <p>25      room either in paper form or on a thumb drive?</p>	<p>1       supplemental reliance list that is printed, it says</p> <p>2       April 5, 2005, which I guess was three days ago.</p> <p>3              (Plaintiff Exhibits No. 3 and 4 were</p> <p>4              marked for identification.)</p> <p>5       A. Yeah.</p> <p>6       BY MR. FREESE:</p> <p>7       Q. Is that right?</p> <p>8       A. That's right.</p> <p>9       Q. Okay. And is Exhibit 4 your supplemental</p> <p>10      reliance list?</p> <p>11      A. Yes, this looks like my reliance list and</p> <p>12      I would say supplemental reliance list.</p> <p>13      Q. Okay, and do you know sitting here what</p> <p>14      was added or subtracted from your supplemental reliance</p> <p>15      list?</p> <p>16      A. This has articles on, on other, other,</p> <p>17      this has articles on biomechanics, and, as I can see</p> <p>18      just flipping through these, these pages, it has my,</p> <p>19      all the things that I relied that I testified on last</p> <p>20      week.</p> <p>21      Q. Okay. Well, what I'm, what I'm trying to</p> <p>22      find out is, is there a way that I can, without going</p> <p>23      line by line, figure out what it is you added to your</p> <p>24      supplemental reliance list on the 5th of April, three</p> <p>25      days ago?</p>
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<p>1       A. I have, I have made an effort to put</p> <p>2       everything there on the floor and I have my thumb</p> <p>3       drive.</p> <p>4       Q. Okay, my question is, is everything that</p> <p>5       you have reviewed and relied on in this case either on</p> <p>6       the thumb drive or on the floor in paper format?</p> <p>7       A. Yes.</p> <p>8       Q. And the only set of documents that have</p> <p>9       been withheld are your 1099s?</p> <p>10      A. Yes.</p> <p>11      MS. GALLAGHER: And, Rich, just to be</p> <p>12      clear, I don't know if all of the literature is</p> <p>13      on this thumb drive, but I think all the</p> <p>14      case-specific materials are on there. I'm just</p> <p>15      not clear if we loaded up all the literature</p> <p>16      again.</p> <p>17      MR. FREESE: Okay.</p> <p>18      BY MR. FREESE:</p> <p>19      Q. And, Doctor, we were provided a</p> <p>20      supplemental reliance list of yours this week. Did you</p> <p>21      realize that?</p> <p>22      A. Yes.</p> <p>23      Q. So, let me go ahead, and I'm going to</p> <p>24      mark what was referenced to us as your reliance list as</p> <p>25      Exhibit 3, and I'm going to mark as Exhibit 4 your</p>	<p>1       A. No, I've been giving articles that I come</p> <p>2       across but I did bring the articles that are not in</p> <p>3       here.</p> <p>4              MS. GALLAGHER: Rich, I might be able to</p> <p>5       short change this. I think the only thing that</p> <p>6       was added were additional medical records that</p> <p>7       didn't make the original list. I don't believe</p> <p>8       there's any additional articles on there, is my</p> <p>9       understanding.</p> <p>10      MR. FREESE: That's what I'm trying to</p> <p>11      find out.</p> <p>12      BY MR. FREESE:</p> <p>13      Q. So, based on what, what Ms. Gallagher</p> <p>14      said, does that sound accurate to you, Doctor, that the</p> <p>15      only supplement has been additional records?</p> <p>16      A. That sounds accurate.</p> <p>17      Q. And in fairness, this reliance list is</p> <p>18      not prepared by you, is it?</p> <p>19      A. No, initially it's given in a packet,</p> <p>20      although I can tell you that most of these articles I</p> <p>21      read through them through the years.</p> <p>22      Q. I understand. I move to strike that.</p> <p>23      That's not really my question, Dr. Sepulveda. These</p> <p>24      reliance lists, Exhibit 3 and Exhibit 4, are prepared</p> <p>25      by lawyers for Ethicon, not by you, correct?</p>

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<p>1        A. That is correct.</p> <p>2        Q. You didn't sit here at your computer and 3 create 70 or 80 pages of single-spaced reliance 4 materials?</p> <p>5        A. I did put together the articles, I did 6 the research for the articles that are included 7 initially on the TVTO summary that is used in this 8 case.</p> <p>9            MR. FREESE: Move to strike.</p> <p>10          BY MR. FREESE:</p> <p>11          Q. Not my question, sir. You didn't sit 12 here and prepare at a computer your reliance materials. 13 That was done by the lawyers, correct?</p> <p>14          A. Yes, on the computer was done by them.</p> <p>15          Q. And then it's attached to your report, 16 correct?</p> <p>17          A. Yes.</p> <p>18          Q. Okay. And your testimony is that you 19 think over the years you've seen or read most of the 20 things on your reliance list?</p> <p>21          A. I would say all of them.</p> <p>22          Q. So you've read all the internal Ethicon 23 documents referenced on your reliance list?</p> <p>24          A. I have a binder that has been provided to 25 me with the TVTO company documents.</p>	<p>1        A. No.</p> <p>2        Q. Okay. So, one hundred percent of the 3 internal documents that you've looked at regarding TVTO 4 or any meshes that you testify about are hand selected 5 and given to you by Ethicon, correct?</p> <p>6        A. Yes.</p> <p>7        Q. All right, Doctor, we're going to go 8 ahead and mark your copy of the -- this is the report 9 prepared in this case, is that correct?</p> <p>10       A. Yes.</p> <p>11       Q. All right, I'm going to mark as Exhibit 12 5 --</p> <p>13       MR. JORDAN: Can we mark this and get a 14 copy of this? I think what we would like to do 15 is just mark it so he can have his original 16 back and we can replace the copy with the depo 17 when we get it. I just want it in the record 18 that he brought this and what it is.</p> <p>19       MS. GALLAGHER: Yeah, that's fine, it's 20 just because trial is so close we just want to 21 get his materials back to him as fast as we 22 can.</p> <p>23       BY MR. FREESE:</p> <p>24       Q. So, I'm going to mark as Exhibit 5 the 25 documents that Ethicon's lawyers provided to you of the</p>
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<p>1        Q. Okay, and did you bring it here with you 2 today?</p> <p>3        A. Yes, I did.</p> <p>4        Q. And do you have a binder of those?</p> <p>5        A. Yes.</p> <p>6        Q. Do you mind grabbing that?</p> <p>7        A. No.</p> <p>8        Q. And would you go ahead and describe 9 what's in this binder for me?</p> <p>10       A. It's a, it's a group of, it's a mixed 11 group of the history of TVTO, the -- I'm not going to 12 read the whole thing.</p> <p>13       Q. That's fine, just a narrative.</p> <p>14       A. But, the summaries of how TVTO was 15 developed.</p> <p>16       Q. Okay. And, again, these were internal 17 documents that were hand picked by the lawyers for 18 Ethicon, is that correct?</p> <p>19       A. They, they were provided to me. I don't 20 know what, what method they used.</p> <p>21       Q. Well, the method was, they chose which 22 documents to supply to you, correct?</p> <p>23       A. I, I think, I think, yes.</p> <p>24       Q. Okay. And is there any specific internal 25 document that you asked them to provide to you?</p>	<p>1        internal records of the company, the binder.</p> <p>2        A. I understand.</p> <p>3            (Plaintiff Exhibit No. 5 was marked for 4 identification.)</p> <p>5        BY MR. FREESE:</p> <p>6        Q. Okay. I'll mark as Exhibit 6 your expert 7 opinion in the Jennifer Ramirez case. 8            (Plaintiff Exhibit No. 6 was marked for 9 identification.)</p> <p>10       BY MR. FREESE:</p> <p>11       Q. Is that correct?</p> <p>12       A. Yes. You mean my marked copy?</p> <p>13       Q. Yes, I want to mark your marked copy.</p> <p>14       A. Yes.</p> <p>15       Q. And these are, the pink stickies are 16 yours?</p> <p>17       A. Yes.</p> <p>18       Q. In your handwriting?</p> <p>19       A. Yes.</p> <p>20       Q. And there's highlighting here also, 21 correct?</p> <p>22       A. Yes.</p> <p>23       Q. Generally, what is it that you 24 highlighted?</p> <p>25       A. Anything that I, I anticipate that you</p>

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<p>1 would ask me about.</p> <p>2 Q. Okay. Fair enough. And I'm going to 3 give it back to you, and I may, I may ask to get it 4 back to see what's highlighted and what the notes say 5 when I get to that particular page. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. Doctor, I'm going to try to do this in 8 just page-flipping order so we can get through this, 9 but am I correct that this expert report is virtually 10 identical to a number of expert reports that you have 11 issued in synthetic mesh litigation lawsuits?</p> <p>12 A. They, the general report, yes.</p> <p>13 Q. The credentials and qualifications would 14 be virtually identical?</p> <p>15 A. Yes.</p> <p>16 Q. Okay, and the general opinions that you 17 hold about TVT and TVTO and TVTS are all virtually 18 identical?</p> <p>19 A. Yes, sir.</p> <p>20 Q. Okay, and then we have some opinions that 21 are specific to Ms. Ramirez's case, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Am I correct, like your reliance 24 list, that your expert report is not prepared by you 25 but rather is prepared by the lawyers for Ethicon?</p>	<p>1 care plan?</p> <p>2 A. If I -- repeat that again, please.</p> <p>3 Q. Yes, sir. There's four pages of, of 4 opinions that you have about the life care plan that 5 you say you did not prepare.</p> <p>6 A. No, I did not type those, and, and those 7 were prepared by the attorney's office and I reviewed 8 them.</p> <p>9 Q. Okay, you reviewed the comments?</p> <p>10 A. Yes.</p> <p>11 Q. Did you review any of the underlying 12 documents that made up the life care plan?</p> <p>13 A. Yes, I reviewed the documents prepared by 14 Mr. Harrell, and I read the deposition of Dr. Elizondo.</p> <p>15 Q. All right, and these are -- were there 16 anything other than those two depositions that you 17 read?</p> <p>18 A. No.</p> <p>19 Q. Did you read the entirety of the 20 depositions?</p> <p>21 A. I, yeah, Elizondo, I read the whole 22 thing.</p> <p>23 Q. Were there portions selected for you by 24 the lawyers, or did you just, you sat down and read the 25 whole deposition?</p>
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<p>1 A. No, that's not correct.</p> <p>2 Q. Okay. So, who actually types this 3 report?</p> <p>4 A. I, I did.</p> <p>5 Q. You typed this 66-page report?</p> <p>6 A. I actually did.</p> <p>7 Q. Okay, and how long did it take you to 8 type this 66-page report?</p> <p>9 A. I'm going to, I'm going to, I misspoke on 10 the, the whole report. The, the part that has to do 11 with the life care plan, I did not type that one.</p> <p>12 Q. Okay. So, the life care plan opinion 13 starts at page 63 of your report?</p> <p>14 A. Yes, that's correct.</p> <p>15 Q. And you did not type that?</p> <p>16 A. No, I did not type the comments on the 17 life care plan.</p> <p>18 Q. Who prepared your comments on the life 19 care plan?</p> <p>20 A. The, the attorney's office.</p> <p>21 Q. Okay. Do you know who in the attorney's 22 office?</p> <p>23 A. No.</p> <p>24 Q. Okay. Did you actually review any 25 underlying records to create the comments in the life</p>	<p>1 A. No, that one I read the whole, whole 2 deposition.</p> <p>3 Q. I can look at your reliance list, but 4 there are a lot of depositions that are listed here. 5 Did you read every one of them?</p> <p>6 A. At some point, I have read them, because 7 being this is so long, this is two years, but yes, I 8 have read the depositions, and they don't all come, as 9 you probably would know, they don't come at one time. 10 They come in sequence.</p> <p>11 Q. So, over the period of Ms. Ramirez's 12 case, you've read several thousands of pages of 13 deposition testimony to form your opinion, correct?</p> <p>14 A. Yes, sir.</p> <p>15 Q. And that would include all of her 16 treating physicians?</p> <p>17 A. Yes, all the treating physicians that 18 I've been made aware of by the medical records.</p> <p>19 Q. Her deposition, correct?</p> <p>20 A. Two, both of them.</p> <p>21 Q. Three of them. Did you know there were 22 three, three installments of her deposition?</p> <p>23 A. No, I read two, two depositions.</p> <p>24 Q. Did you know there were three?</p> <p>25 A. No.</p>

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<p>1       Q. Okay. What two versions did you read?</p> <p>2       A. I read the first and the second</p> <p>3       depositions.</p> <p>4       Q. Okay.</p> <p>5       A. That's the transcript of each one.</p> <p>6       Q. You didn't read the third version?</p> <p>7       A. No.</p> <p>8       Q. So your opinions can't be influenced in</p> <p>9       any way by what she said in her third deposition,</p> <p>10      correct?</p> <p>11      A. No, I have not read it, I cannot rely on</p> <p>12      it.</p> <p>13      Q. And you don't intend to give any opinions</p> <p>14      based on anything that was said in her third</p> <p>15      deposition?</p> <p>16      A. I'm not even aware that there was a third</p> <p>17      deposition, so I definitely could not rely on.</p> <p>18      Q. So anything that was said in the third</p> <p>19      deposition can't form any basis for any opinion you're</p> <p>20      giving, correct?</p> <p>21      A. Unless I read them before trial, and then</p> <p>22      everybody should be aware if anything changes.</p> <p>23      Q. I'm talking about as you sit here today,</p> <p>24      we've got your report, we've got you here under oath</p> <p>25      giving your opinions, you can't opine, don't intend to</p>	<p>1       hospital, and I put together the research, I cooperate</p> <p>2       with the research instruments, I oversee the research</p> <p>3       instruments as the principal investigator. That</p> <p>4       includes IRB submissions and registering in the</p> <p>5       clinicaltrials.gov site.</p> <p>6       Q. But the registry is closed?</p> <p>7       A. Yes, when we finish our project, we are</p> <p>8       required to close that registry or that project on the</p> <p>9       clinicaltrials.gov.</p> <p>10      Q. So you're no longer an investigator for</p> <p>11      that?</p> <p>12      A. No.</p> <p>13      Q. I guess we should take that out of your</p> <p>14      résumé, should we not?</p> <p>15      A. You can actually strike it, yeah.</p> <p>16      Q. Okay. And it says that, the conference</p> <p>17      director for the Pelvic Floor Board. What is that?</p> <p>18      A. The Pelvic Floor Board is a group of</p> <p>19      colorectal, radiologists, physical therapists,</p> <p>20      gastroenterologists, neurologists, urogynecologists,</p> <p>21      gynecologists, and neurologists and pain management</p> <p>22      specialists. We all get together every quarter and we</p> <p>23      present cases, discuss cases and treatment strategies</p> <p>24      and share knowledge.</p> <p>25      Q. Is this national or international, or is</p>
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<p>1       opine on anything said in her third deposition?</p> <p>2       A. No, I have not read it.</p> <p>3       Q. Okay. Now, real quickly, you're the</p> <p>4       medical director of South Miami Medical Arts Surgery,</p> <p>5       correct?</p> <p>6       A. Yes.</p> <p>7       Q. And that's, that's where you work?</p> <p>8       A. That's one of the places where I work.</p> <p>9       That's, that's a surgery center that is a partnership</p> <p>10      between the surgeons and Baptist Health System.</p> <p>11      Q. And what do you do as the medical</p> <p>12      director?</p> <p>13      A. I oversee credentialing, oversee the</p> <p>14      directory for pharmacy, I oversee any incidents,</p> <p>15      incident reports, and I, I also prepare for joint</p> <p>16      commission reviews and AHCA, A-H-C-A, reviews.</p> <p>17      Q. It says you are a principal investigator</p> <p>18      of the Fibroid Registry Research Project. What is</p> <p>19      that?</p> <p>20      A. Yes, that's a registry, it's a research,</p> <p>21      and, it's a research project, and it was registered and</p> <p>22      has been closed.</p> <p>23      Q. What was it a research project of? And</p> <p>24      what was the purpose of the project?</p> <p>25      A. Well, there's a fibroid center at the</p>	<p>1       that just here in Miami?</p> <p>2       A. That's a CME activity. It's one-credit</p> <p>3       CME activity here at Baptist Health.</p> <p>4       Q. Okay, that's what I'm getting at, it's a</p> <p>5       local entity?</p> <p>6       A. That's correct.</p> <p>7       Q. And you set up the conferences for it?</p> <p>8       A. Yes, I'm the conference director.</p> <p>9       Q. Okay. Now, you're a member of the</p> <p>10      American Urologic, Urogynecologic Society, is that</p> <p>11      right?</p> <p>12      A. Yes.</p> <p>13      Q. That is an organization made up of</p> <p>14      doctors who practice urology and gynecology?</p> <p>15      A. Yeah, we, AUGS started in the '90s, and</p> <p>16      it was put together by Dr. Jack Robertson, and he, now</p> <p>17      it's just the society that represents those with an</p> <p>18      interest or a board certification in urogynecologic</p> <p>19      medicine and reconstructive surgery.</p> <p>20      Q. That's commonly referred as to AUGS?</p> <p>21      A. AUGS.</p> <p>22      Q. And am I correct, as long as you're a</p> <p>23      doctor practicing urology or urogynecology and you</p> <p>24      submit your application, you can be a member of the</p> <p>25      organization, correct?</p>

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<p>1 A. That's correct.</p> <p>2 Q. You don't have to take a test to get in</p> <p>3 there?</p> <p>4 A. No.</p> <p>5 Q. You don't have to be invited?</p> <p>6 A. No.</p> <p>7 Q. You're just, I'm a doctor, I do</p> <p>8 gynecology, I do urology, I would like to be a member,</p> <p>9 here's my dues, I'm in, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay, and in fact, Ethicon is a member of</p> <p>12 AUGS, is that correct?</p> <p>13 A. I did not know that.</p> <p>14 Q. Is me telling you, is that the first time</p> <p>15 you ever heard it?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And then it says that you're a</p> <p>18 member of the American Urological Association, AUA, is</p> <p>19 that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Same thing, that's an organization that</p> <p>22 you don't have to be invited to, correct?</p> <p>23 A. No, that one I was invited.</p> <p>24 Q. You don't have to be invited to it,</p> <p>25 correct?</p>	<p>1 Urogynecologic Association?</p> <p>2 A. Yes.</p> <p>3 Q. Is that IUGA?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. What about that organization, do</p> <p>6 you have to be invited to that, or can you simply join</p> <p>7 it?</p> <p>8 A. No, you join.</p> <p>9 Q. Okay, you pay your dues, submit your</p> <p>10 application, Dr. Sepulveda, you're a member, correct?</p> <p>11 A. Yes.</p> <p>12 Q. ICS, International Continence Society,</p> <p>13 that's also a group, that was founded in England,</p> <p>14 right?</p> <p>15 A. I don't know if it was founded in</p> <p>16 England. I know it's a great source of information.</p> <p>17 Q. And that's simply, I'm Jaime Sepulveda</p> <p>18 and I want to be a member, here's my money and here's</p> <p>19 my application, and you're in, correct?</p> <p>20 A. Yes.</p> <p>21 Q. All right, you were not invited to be a</p> <p>22 member of ICS?</p> <p>23 A. No.</p> <p>24 Q. Anybody who is a doctor who pays the dues</p> <p>25 can be a member of ICS, correct?</p>
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<p>1 A. For me as a gynecologist to be a member,</p> <p>2 yes.</p> <p>3 Q. Generally, anyone who is a practicing</p> <p>4 urologist who wants to be a member of the AUA can</p> <p>5 submit an application to be a member, correct?</p> <p>6 A. If you are a urologist.</p> <p>7 Q. That's my point. And you are.</p> <p>8 A. No, I'm a urogynecologist.</p> <p>9 Q. I understand, but you practice urology</p> <p>10 and gynecology, do you not?</p> <p>11 A. I practice female pelvic medicine and</p> <p>12 reconstructive surgery. That's my board certification.</p> <p>13 Q. And, so, any doctor who practices in that</p> <p>14 field can apply, pay a due and be a member of AUA,</p> <p>15 correct?</p> <p>16 A. I think for urologists, they are board</p> <p>17 certified in urology. I am not sure.</p> <p>18 Q. As you sit here today, you didn't have to</p> <p>19 take a test to be an AUA member, did you?</p> <p>20 A. No, for me to be a member, I had to be</p> <p>21 invited and sponsored by a urologist.</p> <p>22 Q. And then you pay your dues and you become</p> <p>23 a member, correct?</p> <p>24 A. Yes.</p> <p>25 Q. All right. The IUA, the International</p>	<p>1 A. Yes.</p> <p>2 Q. Does your experience in neuromodulation</p> <p>3 have anything to do with the opinions you're giving in</p> <p>4 this case?</p> <p>5 A. No, not neuromodulation.</p> <p>6 Q. It's in your report, so I just want to</p> <p>7 make sure, as I go through this, I want to see if it</p> <p>8 impacts your opinions, and if it doesn't, we won't</p> <p>9 spend any time on it.</p> <p>10 A. No, neuromodulation is used for urge</p> <p>11 incontinence, but it's not something that I would</p> <p>12 recommend for Mrs. Ramirez at this time.</p> <p>13 Q. And you said that you have a good bit of</p> <p>14 experience with TTV, TVTO and TTV Secur, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you describe it in your report as</p> <p>17 three generations of TTV products, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And all three of those use the</p> <p>20 same mesh, correct?</p> <p>21 A. Yes.</p> <p>22 Q. The, the method of implanting is</p> <p>23 different, correct?</p> <p>24 A. Yes.</p> <p>25 Q. The length is different?</p>

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<p>1       A. Yes.</p> <p>2       Q. And, but in your mind, those three</p> <p>3       products represent three different generations of, of</p> <p>4       the TVT family of products?</p> <p>5       A. Yes.</p> <p>6       Q. All right. You also implant TTVT</p> <p>7       Abbrevos, do you not?</p> <p>8       A. Yes.</p> <p>9       Q. Is that part of the third generation, or</p> <p>10      is it a fourth generation, or where do you put Abbrevos</p> <p>11      in the hierarchy of --</p> <p>12      A. It's probably, we're going to call it</p> <p>13      fourth generation just by when they came in.</p> <p>14      Q. Okay. It was put on the market in 2010</p> <p>15      after, after the other three, correct?</p> <p>16      A. It might be around that time.</p> <p>17      Q. I'm just curious why you didn't put</p> <p>18      Abbrevos in your report.</p> <p>19      A. I don't know, probably just going the</p> <p>20      Abbrevos in the same, in my mind I think it's the same</p> <p>21      way as the TVTO.</p> <p>22      Q. It's an obturator approach?</p> <p>23      A. It's a transobturator approach with</p> <p>24      midurethral synthetic sling.</p> <p>25      Q. And you put a lot of Abbrevos in, don't</p>	<p>1       Q. Did you ever look up decommercialization</p> <p>2       in the dictionary?</p> <p>3       A. Never looked at it.</p> <p>4       Q. It doesn't exist, I'll invite you to look</p> <p>5       it up. What you mean by decommercialization is, TTVT</p> <p>6       Secur was taken off the market by Ethicon, was it not?</p> <p>7       MS. GALLAGHER: Object to form.</p> <p>8       A. What I consider is that they don't sell</p> <p>9       it anymore.</p> <p>10      BY MR. FREESE:</p> <p>11      Q. That's right, because they don't make it</p> <p>12      anymore and they don't market it anymore, correct?</p> <p>13      A. They don't sell it, they don't market it</p> <p>14      anymore.</p> <p>15      Q. And why don't they market it anymore?</p> <p>16      MS. GALLAGHER: Object to form.</p> <p>17      A. It was a decision that came on, on a</p> <p>18      letter that they explained that, because there were</p> <p>19      other, other -- there was other methodology that was</p> <p>20      going to be used for submission to the FDA. They, they</p> <p>21      could not make it anymore. They decided not to make it</p> <p>22      anymore.</p> <p>23      BY MR. FREESE:</p> <p>24      Q. And they decided not to make it anymore</p> <p>25      because the FDA told them that the FDA was not</p>
<p>1       you?</p> <p>2       A. Yes.</p> <p>3       Q. Okay. You're not putting the Secur in</p> <p>4       anymore, correct?</p> <p>5       A. I don't have it.</p> <p>6       Q. Okay. Because it was taken off the</p> <p>7       market, wasn't it?</p> <p>8       A. I don't have it, I just don't have it</p> <p>9       available.</p> <p>10      Q. I know you don't, and the reason you</p> <p>11      don't have it is because it's not made anymore, is it?</p> <p>12      A. It's not made anymore.</p> <p>13      Q. Because Ethicon took it off the market,</p> <p>14      correct?</p> <p>15      MS. GALLAGHER: Object to form.</p> <p>16      A. Yeah, they decommercialized it.</p> <p>17      BY MR. FREESE:</p> <p>18      Q. Well, decommercialization, is that what</p> <p>19      you mean, they decommercialized it?</p> <p>20      A. Yeah, that's the term that has been used.</p> <p>21      Q. That's not even a word, is it?</p> <p>22      A. I don't know.</p> <p>23      Q. I mean, I'm not trying to be funny.</p> <p>24      Decommercialization is not even a word, is it, Doctor?</p> <p>25      A. I don't know.</p>	<p>1       satisfied with the safety of the TTVT Secur, correct?</p> <p>2       MS. GALLAGHER: Object to form.</p> <p>3       A. I think that it was -- I don't know if it</p> <p>4       was about safety, I think it was more about getting</p> <p>5       post-market surveillance.</p> <p>6       BY MR. FREESE:</p> <p>7       Q. You know that the FDA sent a letter to</p> <p>8       Ethicon saying that it was not satisfied that the</p> <p>9       safety of the TTVT Secur was established and therefore</p> <p>10      the company was going to be required to do 522 studies</p> <p>11      in order to keep marketing the product, and rather than</p> <p>12      do the studies to prove the safety, the company took</p> <p>13      the product off the market, correct?</p> <p>14      MS. GALLAGHER: Object to form.</p> <p>15      A. I know that there was a request for a</p> <p>16      522. I cannot tell you that it was because of safety.</p> <p>17      BY MR. FREESE:</p> <p>18      Q. Well, what else does the FDA regulate</p> <p>19      products for other than safety?</p> <p>20      A. They, they, they do safety, efficacy and</p> <p>21      quality of products.</p> <p>22      Q. Okay, and as you sit here today, do you</p> <p>23      know of anybody disputing the quality of the TTVT Secur?</p> <p>24      A. No.</p> <p>25      Q. Do you know of anybody disputing the</p>

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<p>1 efficacy of the TTV Secur?</p> <p>2 A. No.</p> <p>3 Q. You do know that they were disputing the</p> <p>4 safety of the TTV Secur, correct?</p> <p>5 A. I do not know that.</p> <p>6 Q. As you sit here today, you have no idea</p> <p>7 why the company took the TTV Secur off the market?</p> <p>8 A. I, I don't have a clear idea why.</p> <p>9 Q. And does the 522 order relate to the</p> <p>10 safety of a product or the efficacy of a product?</p> <p>11 A. I think it has to do with post-market</p> <p>12 surveillance.</p> <p>13 Q. And is post-market surveillance focused</p> <p>14 on safety or efficacy?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I already say I don't know if it's about</p> <p>17 safety. I know a post-market surveillance is a lot</p> <p>18 more involved than just safety.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. You think post-market surveillance has to</p> <p>21 do with the efficacy of a product?</p> <p>22 A. I believe it does.</p> <p>23 Q. And you think the criticism that the FDA</p> <p>24 had in the post-market surveillance of TTV Secur was</p> <p>25 because of the efficacy of the product?</p>	<p>1 Q. All right. Look at page 4, if you don't</p> <p>2 mind, sir.</p> <p>3 MS. GALLAGHER: What document are you</p> <p>4 looking at?</p> <p>5 MR. FREESE: I'm looking at this</p> <p>6 document.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. Is that the same one you're looking at?</p> <p>9 A. Yes, this is the FDA Executive Summary</p> <p>10 for surgical mesh for treatment of women with pelvic</p> <p>11 organ prolapse and stress urinary incontinence.</p> <p>12 Q. Look at page 4, section 2.3, regarding</p> <p>13 522 post-market surveillance studies.</p> <p>14 A. I'm looking at page 4.</p> <p>15 Q. Okay. Is this what you needed to look at</p> <p>16 to answer the question?</p> <p>17 A. No, I was looking at the decision of the</p> <p>18 committee on the post-market option. Yes. What would</p> <p>19 you like me to read?</p> <p>20 Q. My question is, the post-market</p> <p>21 surveillance studies that the FDA had required Ethicon</p> <p>22 to conduct related to the serious adverse health</p> <p>23 consequences that may be caused by a failure of the</p> <p>24 product, correct?</p> <p>25 A. About the, about the efficacy and safety</p>
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<p>1 MS. GALLAGHER: Object to the form.</p> <p>2 A. There was a, there was a, now that you</p> <p>3 mentioned it -- can I refer to one of my documents?</p> <p>4 Because it's in my, it's in one of the documents that I</p> <p>5 brought.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Sure. Do you need to look at a document</p> <p>8 to answer my question?</p> <p>9 A. Well, we have been talking about the same</p> <p>10 question already in four separate instances, and if I'm</p> <p>11 going to answer your question accurately I would like</p> <p>12 to refer to my document.</p> <p>13 Q. You mean four separate depositions you've</p> <p>14 given?</p> <p>15 A. I don't understand your question.</p> <p>16 Q. I don't understand your answer. You said</p> <p>17 we've been talking about it in four separate instances.</p> <p>18 What did you mean, sir?</p> <p>19 A. Well, you asked me already about safety</p> <p>20 and that the 522 has to do with safety, and before I</p> <p>21 give you an answer I want to make sure that I give you</p> <p>22 an accurate answer, and I want to see the document.</p> <p>23 Q. Go ahead.</p> <p>24 A. I'm looking at the white paper from the</p> <p>25 FDA.</p>	<p>1 and quality.</p> <p>2 Q. About the, the 522 allows the FDA to</p> <p>3 order the study where the failure of the device was</p> <p>4 reasonably likely to have a serious adverse health</p> <p>5 consequence. Correct?</p> <p>6 A. Are you reading on the pelvic organ</p> <p>7 prolapse section?</p> <p>8 Q. I'm reading page 4 on 522 studies.</p> <p>9 A. Yes. Well, I'm going to read on page 47,</p> <p>10 which is a more specific question about TTV Secur.</p> <p>11 Q. Okay. Go ahead.</p> <p>12 A. The panel will be asked to consider</p> <p>13 whether 522 studies are needed for cleared mini-slings,</p> <p>14 all cleared surgical mesh indicated for stress urinary</p> <p>15 incontinence, not needed for these devices. If the</p> <p>16 panel believes 522 are needed for all or just a subset</p> <p>17 of these products, the panel will be asked to discuss</p> <p>18 the type clinical study that should be required with</p> <p>19 consideration to patient selection, controls,</p> <p>20 randomizations, outcome measures, concomitant</p> <p>21 surgeries, follow-up duration, etcetera.</p> <p>22 Q. Okay, and you agree with the FDA</p> <p>23 statements in the summary about the TTV Secur?</p> <p>24 A. I, I agree that they are in all the power</p> <p>25 to choose whatever method they decide to choose.</p>

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<p>1       Q. I understand, but do you agree with the 2 comments that they made about the safety of the TVT 3 Secur?</p> <p>4       A. I don't think that TVT Secur is an unsafe 5 procedure; therefore, I see no reason to go beyond what 6 was already being done. Now, I do understand that will 7 benefit from surveillance in any product in which there 8 are being reports of any, any type of incident.</p> <p>9       Q. Rather than do the post-market 522 10 studies, the company, rather than approve the safety of 11 the product through those post-market studies, chose to 12 take it off the market, correct?</p> <p>13      MS. GALLAGHER: Object to form.</p> <p>14      A. The safety of the product has been, is 15 already being examined independently from the FDA. 16 There have been through, there have been studies 17 through separate, separate studies and trials. What 18 they, the FDA decided was to do 522 because that's a 19 mechanism that they have in place.</p> <p>20 BY MR. FREESE:</p> <p>21      Q. All you're saying is the FDA did what 22 they have the right to do. I'm asking you if you 23 agreed with what they did.</p> <p>24      MS. GALLAGHER: Object to form.</p> <p>25      A. I, I disagree with the methodology of the</p>	<p>1       A. That's correct. I think it's based on 2 the best science that they consider, but there's a bias 3 on the methodology to come to their conclusions and 4 recommendations.</p> <p>5       Q. Can you describe to me, Dr. Sepulveda, 6 what bias the FDA has?</p> <p>7       A. Well, it's a very small group, and, and 8 it's, it's a group, I believe it's 12, 12 individuals, 9 and the methodology used on the statistical analysis 10 was not, was not fully, fully completed, fully 11 disclosed, I should have said, fully disclosed. Also, 12 the way the complaints were examined, from the MAUDE, 13 from the MAUDE database was put through an Excel 14 program, it was required to be placed on an Excel 15 program to trim down the repeated complaints. So, the 16 MAUDE database was used but there's, within itself has 17 its own, its own limitations.</p> <p>18      I'm going to, I'm going to, I'm going to 19 read the limitations of the MAUDE data analysis, which 20 is on the FDA reports, in which it says the reports 21 were unduplicated using Excel on duplication function, 22 not by reviewing the individual reports. A few 23 unduplicated reports might still exist in the data. 24 This auto function does not exemplify reports that have 25 different numbers but are related to the same events.</p>
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<p>1       FDA which has proven to this time to be inadequate to 2 regulate and innovate at the same time. This type of 3 criminology of 522s or 510(k)s have been in place for a 4 long period of time, and it's, there's a consensus that 5 this need to be reviewed. Now, at the time that this 6 was decided, all this consensus came through, the 522 7 was the mechanism in place.</p> <p>8 BY MR. FREESE:</p> <p>9       Q. Right. You read the executive summary, 10 did you not?</p> <p>11      A. I did.</p> <p>12      Q. And you read it in forming your opinions 13 in this case?</p> <p>14      A. Yes.</p> <p>15      Q. And you agree with all the, the FDA 16 statements in the summary?</p> <p>17      A. No, I don't agree with all of them and I 18 don't disagree with all of them.</p> <p>19      Q. You disagree with some and agree with 20 others?</p> <p>21      A. There are parts in which I have no 22 opinion.</p> <p>23      Q. I guess it would be fair to say you don't 24 think that FDA statements are always well founded in 25 science, correct?</p>	<p>1       If one event has two reports, one from the manufacturer 2 and one from voluntary reporter, but they are not 3 linked in the MAUDE database as one event, they will 4 not be taped by auto function as one event.</p> <p>5       So, that tells you the accuracy of the 6 data that was obtained on, on, on this recommendations.</p> <p>7       In addition, even though the result of 8 data mining were refined multiple times, it is still 9 possible that a few reports are placed in the wrong 10 group and in the wrong adverse event group.</p> <p>11      I just read the way, the way the FDA 12 itself, the group, says that there's a limitation about 13 data analysis. That is biased.</p> <p>14      Q. And, therefore, you think that 15 conclusions that the FDA reached are unreliable?</p> <p>16      A. I think that they were biased.</p> <p>17      Q. Okay, and therefore, if they're biased, 18 they're unreliable, correct?</p> <p>19      A. They're not accurate.</p> <p>20      Q. And if they're not accurate, they're not 21 reliable?</p> <p>22      A. If you want to equate accurate with 23 reliable, yes.</p> <p>24      Q. I just want to see if you agree with me.</p> <p>25      A. Well, reliable is more, is no more the</p>

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<p>1 word of accuracy. Reliable is how good the 2 methodology and conclusions are.</p> <p>3 Q. And if methodology is biased, that would 4 lead to unreliable results, correct?</p> <p>5 A. I think that most people would judge it 6 as unreliable.</p> <p>7 Q. I mean, you understand evidence-based 8 medicine, correct?</p> <p>9 A. Yes.</p> <p>10 Q. If you're practicing evidence-based 11 medicine, you don't want unreliable data to rely on, do 12 you?</p> <p>13 A. No, I want the most accurate data that I 14 can obtain.</p> <p>15 Q. And, therefore, bias would be a type of 16 unreliable data, correct?</p> <p>17 MS. GALLAGHER: Object to form.</p> <p>18 A. There's no cohort methodology, there's no 19 randomization, there's no actual analysis conducted on 20 this. The whole, the whole concept of evaluating 21 either efficacy or quality in general, in general, I'm 22 talking in general now, in general, we already 23 mentioned for mini-slings and now we're talking in 24 general, in general is that the amount of database is 25 not accurate, and if it's not accurate, you cannot</p>	<p>1 you have had over 500 surgeons visit your operating 2 room to watch you place slings, correct?</p> <p>3 A. Yes.</p> <p>4 Q. How many of those were sponsored by 5 Ethicon?</p> <p>6 A. I think that the majority of them.</p> <p>7 Q. Well, I mean, like 99 percent or 51 8 percent?</p> <p>9 A. I never run a percentage of it, but I 10 have had, I have had surgeons that come without, 11 without Ethicon. The majority could be more than 50 12 percent. This, this pelvic floor, pelvic floor surgery 13 and the specific procedures did not start with mesh. 14 We were doing this procedures and we were using 15 different procedures even before mesh. In the same way 16 that I visited many surgeons, even before there was 17 mesh, they also visited me.</p> <p>18 Q. Okay. Well, did you place any 19 midurethral slings that weren't synthetic?</p> <p>20 Midurethral slings by definition are synthetic slings, 21 are they not?</p> <p>22 A. Yes, there's no data that indicates that 23 midurethral slings should be anything but synthetic.</p> <p>24 Q. I understand. My question, Doctor, I'm 25 asking you about your report, and you said 500 doctors</p>
<p style="text-align: center;">Page 43</p> <p>1 consider reliable.</p> <p>2 BY MR. FREESE:</p> <p>3 Q. Thank you. And, Dr. Sepulveda, do you 4 think that you are more qualified to assess the safety 5 and efficacy of mesh products than the FDA?</p> <p>6 A. I, I cannot substitute a panel of 12 7 people. I cannot substitute a cohort study. It's not 8 that I'm more qualified. I, I am the receiving end of 9 it. So, I can tell you in this receiving end how I can 10 use it.</p> <p>11 Q. Okay, that's not really my question. My 12 question is, do you think that you're more qualified to 13 assess the safety and efficacy of mesh products than 14 the FDA, yes or no?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I have, I have the experience with 17 working with mesh, I have the knowledge on the 18 biomechanics of mesh, I have the knowledge on the 19 conditions that require the mesh, and I have 25 years 20 doing surgery, but that still leaves me in the 21 receiving end of it. Am I more qualified than the FDA? 22 I think I am as qualified as anyone that was in that 23 panel or that spoke to the FDA.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. Now, Doctor, you said in your report that</p>	<p style="text-align: center;">Page 45</p> <p>1 have come to my operating room to watch Dr. Sepulveda 2 put in midurethral slings. You did say that, did you 3 not?</p> <p>4 A. No, not just midurethral slings.</p> <p>5 Q. Well, let's look at your report, sir.</p> <p>6 Page 2, quote, "I have had over 500 physicians visit my 7 operating room to watch me place midurethral slings." 8 Did you write that?</p> <p>9 A. Midurethral slings along with other 10 procedures.</p> <p>11 Q. That's not what your report says, is it, 12 Doctor? Is it?</p> <p>13 A. No, it's not what my report says.</p> <p>14 Q. What your report says is 500 doctors have 15 come to your OR to watch you place midurethral slings, 16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. That means 100 percent of those 500 19 doctors would be watching you place a synthetic 20 midurethral sling, correct?</p> <p>21 A. Yes, they have watched me place a 22 midurethral sling, correct.</p> <p>23 Q. Okay. How many of these 500 doctors that 24 came to watch you put synthetic slings in were 25 sponsored by Ethicon?</p>

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<p>1        A. The majority.</p> <p>2        Q. Is it closer to 500 or is it closer to</p> <p>3        250?</p> <p>4        A. It might be a number between the both of</p> <p>5        them, but I can not give you an accurate number because</p> <p>6        I never recorded it.</p> <p>7        Q. Okay. How do you know it's 500 then, if</p> <p>8        you never recorded it?</p> <p>9        A. Because that's the number, that's the</p> <p>10      number that -- it may have been a thousand.</p> <p>11      Q. Okay.</p> <p>12      A. It may have been a thousand, may have</p> <p>13      been 400, but I can tell you that at least 500, because</p> <p>14      in 25 years doing surgery and you have individuals</p> <p>15      coming to watch you.</p> <p>16      Q. Did you just pick the 500 out of the air?</p> <p>17      A. Yeah, that's the safest number I could</p> <p>18      pick. I could have picked a larger number, though.</p> <p>19      Q. Okay. And how many years have you been</p> <p>20      doing midurethral slings?</p> <p>21      A. It's since TVT came out.</p> <p>22      Q. 1998?</p> <p>23      A. Yes.</p> <p>24      Q. All this 25-year stuff you're talking</p> <p>25      about has nothing to do with when you're talking about</p>	<p>1        that come and watch me place it. That's essentially.</p> <p>2        I could go on with a list, but I don't keep a registry.</p> <p>3        Q. All right. And when, when Ethicon</p> <p>4        sponsors these doctors to come watch you place slings,</p> <p>5        is Ethicon paying you to do that?</p> <p>6        A. Yes, they, they, they were, those were</p> <p>7        mostly activities in which I demonstrated how to place</p> <p>8        product, and some patients with product also had a</p> <p>9        midurethral sling.</p> <p>10      Q. Okay, but when these doctors that are</p> <p>11      sponsored by Ethicon are coming in, you're being paid</p> <p>12      by Ethicon to let them come into your OR to watch you</p> <p>13      do surgeries?</p> <p>14      A. Yeah, they compensate me for my time</p> <p>15      before I do my surgery. When I'm doing my surgery, I'm</p> <p>16      being compensated for my surgery.</p> <p>17      Q. Now, you say that you, you've used</p> <p>18      laser-cut mesh and mechanically-cut mesh, correct?</p> <p>19      A. Yes.</p> <p>20      Q. If I'm holding a TVTO box, for example,</p> <p>21      all right, how can I tell if it's a mesh, if the mesh</p> <p>22      is laser cut or mechanically cut?</p> <p>23      A. I don't know by looking at the box</p> <p>24      because when I'm scrubbed, I'm not looking at a box but</p> <p>25      I look at the product.</p>
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<p>1        midurethral slings, does it?</p> <p>2        A. No, we, we actually dissected the</p> <p>3        urethra, so that -- okay, yes --</p> <p>4        Q. Just answer my question, Doctor. All of</p> <p>5        this talk about I've been doing this 25 years has no</p> <p>6        application to midurethral slings, does it?</p> <p>7        A. Yes, I have not placed midurethral slings</p> <p>8        for 25 years.</p> <p>9        Q. Because they've only been on the market</p> <p>10      for 18 years, correct?</p> <p>11      A. That is correct.</p> <p>12      Q. Okay, and no 500 doctors have seen you</p> <p>13      place a midurethral sling?</p> <p>14      A. It might be 500, it might be more.</p> <p>15      Q. And who comes and sees you place</p> <p>16      midurethral slings in the OR other than people</p> <p>17      sponsored by Ethicon?</p> <p>18      A. I have, I have colleagues that come in, I</p> <p>19      do Miami, they come to Miami, and they say I'm going to</p> <p>20      go and see Jaime do surgery. The first one that comes</p> <p>21      to mind is the chairman, the director of gynecologic</p> <p>22      surgery at the University of Puerto Rico. Another</p> <p>23      colleague in Savannah. Another colleagues also from</p> <p>24      Puerto Rico that is doing academics. I have had</p> <p>25      fellows, I have had residents from other institutions</p>	<p>1        Q. Okay. So, you're an expert, you hold</p> <p>2        yourself out as an expert in TVTO, correct?</p> <p>3        A. Right.</p> <p>4        Q. And we can agree that if you're looking</p> <p>5        at the box, even you, who implants them all the time,</p> <p>6        you don't know if it's mechanical cut or laser cut?</p> <p>7        A. I think that there's a way to know it. I</p> <p>8        just never looked at that box.</p> <p>9        Q. But sitting here today, you can't think</p> <p>10      of what that way is?</p> <p>11      A. Yeah, I look at the sling.</p> <p>12      Q. Okay, you pull it out and you look at it,</p> <p>13      so you don't know until you open the box, pull back</p> <p>14      the, the plastic cover to figure out if it's laser cut</p> <p>15      or mechanical cut?</p> <p>16      A. No, not with the plastic cover. You can</p> <p>17      actually see it on the sheet.</p> <p>18      Q. But you have to open the plastic</p> <p>19      container to get to the TVTO, do you not?</p> <p>20      A. No, it's transparent. You can actually</p> <p>21      see it without even opening it.</p> <p>22      Q. Well, the body is transparent, the top is</p> <p>23      not transparent, is it?</p> <p>24      A. The body, yeah, all the other sides are</p> <p>25      transparent.</p>

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<p>1       Q. The tub is transparent but the top is 2       not?</p> <p>3       A. No, the top is like a paper with a name.</p> <p>4       Q. And you can look through the plastic tub 5       and tell if it's laser cut or mechanical cut?</p> <p>6       A. You can look at the sling in that area, 7       yes.</p> <p>8       Q. Without opening it?</p> <p>9       A. Without opening it.</p> <p>10      MS. GALLAGHER: Y'all are talking about 11      different things. He's talking about the top 12      of the box. Can you look through the top of 13      the box and tell whether it's laser cut or 14      machine cut?</p> <p>15      THE WITNESS: No.</p> <p>16      MR. FREESE: I understand what he was 17      saying.</p> <p>18      BY MR. FREESE:</p> <p>19      Q. You're saying you can look through the 20      clear plastic portion of the TVT before you even open 21      the tub and tell if it's laser cut or mechanical cut?</p> <p>22      A. I have used it so many times and I have, 23      and there's a plastic cover in there, and you can see 24      the whole device right through there. It's, it's, if I 25      tell you, though, in order to be accurate with you, I</p>	<p>1       A. No, I have ordered just, just give me 2       five TVTOs. Actually, you know, I don't tell someone I 3       need TVTOs. Someone keeps my TVTOs there and, and, and 4       I don't, I don't order like I would say that I order 5       things for my office, no.</p> <p>6       Q. Okay, but what I'm getting at is, when 7       you, I mean, you are the doctor and if a TVTO is needed 8       to be implanted in your patient, do you know whether or 9       not it's a laser cut or mechanical cut?</p> <p>10      A. Well, I look at it.</p> <p>11      Q. At the time of the placement?</p> <p>12      A. At the time that I have it there.</p> <p>13      Q. Yes, sir, what I'm trying to find out is 14      at the time that you buy it from Ethicon, are you 15      dictating it be one or the other?</p> <p>16      A. No.</p> <p>17      Q. Who does that?</p> <p>18      A. They, they, they order it from, from the 19      company. There's no one that determines laser cut or 20      mechanical cut.</p> <p>21      Q. And it doesn't make any difference to you 22      which one it is?</p> <p>23      A. No.</p> <p>24      Q. Am I correct that after the TVTO laser 25      cut was introduced, Ethicon introduced several more</p>
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<p>1       cannot tell you that I look right through there and 2       say, okay, which one is that, laser cut or mechanical 3       cut.</p> <p>4       Q. I'm asking you, are you able to do that?</p> <p>5       A. I will have to look at it, because as I 6       sit here today, I don't remember looking through it.</p> <p>7       Q. When you open it and pull it out, it's 8       got a plastic sheath on it, does it not?</p> <p>9       A. It does.</p> <p>10      Q. Well, can you see the edges?</p> <p>11      A. Yes.</p> <p>12      Q. And you can tell if it's laser cut or 13      mechanical cut without ever pulling the plastic sheath 14      back?</p> <p>15      A. Yes.</p> <p>16      Q. Okay. Is there any study that you have 17      looked at that compared how laser-cut versus 18      mechanical-cut mesh performs?</p> <p>19      A. No.</p> <p>20      Q. Do you order the slings, Doctor, that you 21      implant in your patients?</p> <p>22      A. No, the hospital orders it.</p> <p>23      Q. When, when you order them, do you tell 24      the hospital I need five TVTOs, or do you say, I need 25      five TVTO laser cut or five TVTO mechanical cut?</p>	<p>1       synthetic sling products, correct?</p> <p>2       A. I overheard on the, on the different 3       conferences and activities by Ethicon that there was, 4       they were talking about laser cut and mechanical cut. 5       It never made a difference to me, laser cut or 6       mechanical cut.</p> <p>7       Q. And is that -- it's fair to say then that 8       you've actually never studied the clinical differences 9       between laser cut and mechanical cut?</p> <p>10      A. No, there has been no actual clinical 11      studies to my knowledge, and if you have something that 12      I don't know, please, I will read it.</p> <p>13      Q. Sure, and that's fine, Doctor, but my 14      question to you is, and I think you may have told me, 15      there are no studies comparing laser cut to mechanical 16      cut and you have not endeavored in forming your 17      opinions in this case to do any studies on the 18      difference from a clinical standpoint of laser cut 19      versus mechanical cut, correct?</p> <p>20      A. To my knowledge, there has not been a 21      randomized control trial comparing laser cut versus 22      mechanical cut.</p> <p>23      Q. Yes, sir, I understand that, and nor have 24      you done any kind of literature search to see if 25      there's any literature, even if it's not a randomized</p>

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<p>1 control trial, correct, about the difference between 2 mechanical cut versus laser cut?</p> <p>3 A. No, there's no -- I actually look for 4 mechanical cut versus laser cut, and what I have is 5 what's in the company documents.</p> <p>6 Q. So the only documents you've looked at 7 that discuss the difference between mechanical cut and 8 laser cut is what the company lawyers supplied you?</p> <p>9 A. Yes, the company documents.</p> <p>10 Q. And you've done no other independent 11 literature review or scientific review of any 12 literature on any difference that may exist between 13 laser cut and mechanical cut from a clinical 14 standpoint?</p> <p>15 A. I did an PubMed search and I could not 16 find any.</p> <p>17 Q. Okay. The only documents that you have 18 looked at comparing laser cut to mechanical cut are the 19 internal documents of Ethicon, correct?</p> <p>20 A. That is correct.</p> <p>21 MR. FREESE: Let's take a break. (Break taken from 10:25 to 10:30 a.m.)</p> <p>23 BY MR. FREESE:</p> <p>24 Q. Dr. Sepulveda, before our break we were 25 talking about laser cut versus mechanical cut, and real</p>	<p>1 midurethral sling that Ethicon manufactured after the 2 introduction of TVTO that was anything other than 3 laser-cut mesh, correct?</p> <p>4 A. I cannot think of any other.</p> <p>5 Q. And do you have any explanation why that 6 was, why they don't make mechanically-cut mesh in any 7 of the products once laser-cut TVTO became available?</p> <p>8 MS. GALLAGHER: Object to form.</p> <p>9 A. I did not know the reason for it.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. Okay. Doctor, in your overview and 12 review of literature, you say stress urinary 13 incontinence is a common condition in women, and we can 14 look at some data, but am I correct that, that AUA said 15 that up to 50 percent of women will suffer some form of 16 the SUI in their lifetime?</p> <p>17 A. I read that, yes.</p> <p>18 Q. And you agree with that?</p> <p>19 A. I would agree with that.</p> <p>20 Q. It's that common of a problem?</p> <p>21 A. It is a very common problem, yes.</p> <p>22 Q. You say all procedures, but in 23 particular, you say earlier procedures, in other words 24 pre, pre-midurethral sling procedures I gather is what 25 you're talking about here?</p>
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<p>1 quickly, I am correct that after TVTO laser cut was 2 introduced, Ethicon introduced TVT Secur, correct?</p> <p>3 A. Yes.</p> <p>4 Q. TTVT Abbrevio, correct?</p> <p>5 A. Yes.</p> <p>6 Q. TTVT Exact, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Am I also correct that after TVTO laser 9 cut was introduced, Ethicon never introduced another 10 mechanically-cut synthetic midurethral sling again, am 11 I correct?</p> <p>12 A. I, I could not track, but I take it as 13 you're telling me.</p> <p>14 Q. You agree with me that TTVT Secur is laser 15 cut, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Every version of it?</p> <p>18 A. Yes.</p> <p>19 Q. TTVT Exact is laser cut, is it not, every 20 version of it?</p> <p>21 A. Yes.</p> <p>22 Q. TTVT Abbrevio is laser cut, every version 23 of it, correct?</p> <p>24 A. Yes.</p> <p>25 Q. So you cannot think of a single</p>	<p>1 A. Yes.</p> <p>2 Q. Carry the risk of urinary outlet 3 obstruction, voiding dysfunction, major nerve and 4 vascular injuries, pain, relatively high frequency of 5 revision and wound healing complications?</p> <p>6 A. Yes.</p> <p>7 Q. No previous surgery prior to midurethral 8 slings caused a risk of erosion, am I correct?</p> <p>9 A. No, there was exposure of the sutures, we 10 did see that, and we did see sutures inside the 11 bladder.</p> <p>12 Q. Okay. That's not my question. My 13 question is that erosion of the midurethral sling is a, 14 is a, is a complication unique to midurethral slings, 15 synthetic midurethral slings, correct?</p> <p>16 A. Yes, exposure of the tape was not seen 17 before when tapes were not being used.</p> <p>18 Q. Okay, and, Doctor, you say that Burch 19 colposuspensions had earlier been associated with the 20 term gold standard which established a clinical 21 benchmark of efficacy for the treatment of SUI. You 22 see that?</p> <p>23 A. Yes.</p> <p>24 Q. I'm read some of your prior depositions, 25 so I'm going to try to speed through some of this.</p>

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<p>1 You're not a fan of the phrase gold standard, are you?</p> <p>2 A. Never been much of a fan of that.</p> <p>3 Q. So you're not going to come into court</p> <p>4 and start giving us opinions that the TVTO is the gold</p> <p>5 standard of anything, correct?</p> <p>6 A. I would refer to anything that was</p> <p>7 referred before as a gold standard as the current</p> <p>8 clinical standard.</p> <p>9 Q. Current standard, and in fact, there have</p> <p>10 been articles published in the New England Journal of</p> <p>11 Medicine that say you shouldn't use the word gold</p> <p>12 standard, you should use the word current standard,</p> <p>13 correct?</p> <p>14 A. Yes, it was in -- I don't know if it was</p> <p>15 in the New England Journal of Medicine, but it was</p> <p>16 definitely in the AUGS Journal.</p> <p>17 Q. Okay. And you agree that that's a more</p> <p>18 appropriate phrase to use?</p> <p>19 A. Current clinical standard seems to be a</p> <p>20 more objective way of looking at things.</p> <p>21 Q. And, so, when you come to San Antonio to</p> <p>22 testify, is it fair to say that you're not going to be</p> <p>23 sitting there pontificating about gold standards,</p> <p>24 that's just not a term that you think is appropriate?</p> <p>25 A. I agree, I would not be pontificating</p>	<p>1 trial.</p> <p>2 Q. All right, and the reason I asked you</p> <p>3 about gold standard is because about three pages later</p> <p>4 you then invoke the gold standard language on the TVT.</p> <p>5 A. I actually saw that on my report, and I,</p> <p>6 I apologize for that. That should be current clinical</p> <p>7 standards.</p> <p>8 Q. Okay, and that's fine, and fair enough.</p> <p>9 So, even though you have it in your report, you won't</p> <p>10 be referring to the TVTO as the gold standard?</p> <p>11 A. I'm going to repeat my answer, I will not</p> <p>12 be pontificating about gold standard. I will be saying</p> <p>13 current clinical standards.</p> <p>14 Q. Thank you, sir. You have no idea how</p> <p>15 much time that saved us.</p> <p>16 Doctor, when you say, quote, "The use of</p> <p>17 monofilament, non-absorbable polypropylene predominates</p> <p>18 in the current clinical practice," you're not</p> <p>19 distinguishing between mechanical cut and laser cut?</p> <p>20 A. I'm not distinguishing between one or the</p> <p>21 other.</p> <p>22 Q. Am I correct that in that sentence there,</p> <p>23 when you say that those monofilament non-absorbables</p> <p>24 predominate the current clinical practice, you're</p> <p>25 lumping mechanical cut and laser cut meshes together?</p>
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<p>1 about the gold standard.</p> <p>2 Q. Okay, thank you. Doctor, you said that</p> <p>3 the studies in the medical literature prior to the</p> <p>4 midurethral sling, prior to the arrival of TVT were</p> <p>5 lacking and of poor quality. Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And I'm just, I'm just trying to figure</p> <p>8 out, what is your basis for saying that the studies</p> <p>9 prior to TVT were of poor quality?</p> <p>10 A. Well, there were, there were</p> <p>11 retrospective cohort studies that were case reports,</p> <p>12 there were groups of case reports, but there was a lack</p> <p>13 of randomized control trials.</p> <p>14 Q. Is this just simply, and -- strike that.</p> <p>15 The lack of a substantial number of</p> <p>16 randomized control studies is, is how you reached the</p> <p>17 conclusion that the study quality is poor?</p> <p>18 A. Right.</p> <p>19 Q. In other words, you have to have a</p> <p>20 significant number of randomized control studies in</p> <p>21 order to have good-quality data, in your mind?</p> <p>22 A. I look at the, at the cohort studies</p> <p>23 and there are instances in which I may not have a</p> <p>24 randomized control trial. I would like to see multiple</p> <p>25 cohort studies if I don't have a randomized control</p>	<p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. As they are available, because we don't</p> <p>4 have it available anymore in the mechanical cut.</p> <p>5 Q. When did Ethicon stop making TVTO</p> <p>6 mechanical cut?</p> <p>7 A. I, I, I cannot recall one specific date,</p> <p>8 no.</p> <p>9 Q. So, let me clarify that. So, as of</p> <p>10 today, you think all TVTOs are laser cut?</p> <p>11 MS. GALLAGHER: Object to form.</p> <p>12 A. Yes.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. And you don't know exactly when Ethicon</p> <p>15 stopped manufacturing TVTO mechanical-cut mesh?</p> <p>16 MS. GALLAGHER: Object to form.</p> <p>17 A. I don't know a specific date.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. And is that why you said you don't</p> <p>20 concern yourself with it, because it's only laser cut,</p> <p>21 right?</p> <p>22 A. It's only laser cut now.</p> <p>23 Q. All right, thank you. Doctor, you say</p> <p>24 that, quote, "These anatomical considerations," and I'm</p> <p>25 on page 8 of your report if you want to follow along</p>

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<p>1       with me. Quote, "These anatomical considerations were 2       well documented during the description and the design 3       of the TVTO." Do you see that?</p> <p>4       A. Okay, yes. These anatomical 5       considerations were well documented during the 6       description and design of the TVTO. I am talking about 7       the hammock of the, in the suburethra and the 8       periurethral tissue.</p> <p>9       Q. All right, and we can agree that prior to 10      the launch of the TVTO, there were no randomized 11      controlled studies of that product done, correct?</p> <p>12      A. No.</p> <p>13      Q. Okay, and the product was launched in the 14      U.S. and worldwide without a single randomized control 15      study being performed by Ethicon, correct?</p> <p>16      A. It was, it was released on a 510(k) 17      approval.</p> <p>18      Q. And, so, the answer to my question is, at 19      the time the TVTO was released to the world by Ethicon, 20      there were no randomized control studies demonstrating 21      the safety or efficacy of the product, correct?</p> <p>22      A. That's correct.</p> <p>23      Q. And the prelaunch studies that Dr. de 24      Laval performed didn't even use the same kit that 25      became the TVTO, did it?</p>	<p>1       A. He's the inventor.</p> <p>2       Q. And you know he had an economic stake in 3       the results that he reported on his clinical data, 4       correct?</p> <p>5       A. Yeah, you know, I was asked the same 6       question last week, and these are high-caliber 7       investigators. I have no reason to believe that they 8       are going to be biased specifically by money. I cannot 9       say, I cannot sit here and testify under oath that I 10      believe that that's the case.</p> <p>11      Q. Okay. Well, I'm simply asking you, you 12      recognize that the only clinical data that existed was 13      that produced by the guy who had an economic stake in 14      the outcome of these results, correct?</p> <p>15      A. That's correct.</p> <p>16      Q. Okay. And that data was based on his own 17      pre-cut invention, not what ultimately became TVTO, 18      correct?</p> <p>19      A. His own device.</p> <p>20      Q. In other words, de Laval was using a 21      homemade product when he was implanting women with the 22      his obturator-approach midurethral sling, correct.</p> <p>23      MS. GALLAGHER: Object to form.</p> <p>24      A. I don't think he made it at home. He may 25      have made it elsewhere, but I --</p>
<p style="text-align: center;">Page 63</p> <p>1       A. I think that the needles were, were 2       different.</p> <p>3       Q. Okay. And he was, he was, he was cutting 4       it himself, correct?</p> <p>5       A. He may have cut it himself, I'm not aware 6       of which methodology he used for that.</p> <p>7       Q. Because there was no kit for him to 8       implant in women, he created it, correct?</p> <p>9       A. He created it.</p> <p>10      Q. And just so we're clear, Doctor, my 11      question may have lent us to RCTs. At the time that 12      the TVTO was launched by Ethicon, there were no 13      clinical studies whatsoever on the TVTO, correct?</p> <p>14      A. There were, there were the studies from 15      the, from the inventor, and there was data on the TTVT.</p> <p>16      Q. And I'm not talking about TTVT now, 17      because that's a different product, isn't it?</p> <p>18      A. That, that is, there's a different site 19      on the anatomy where it's inserted.</p> <p>20      Q. And it's implanted differently, correct?</p> <p>21      A. It is implanted different.</p> <p>22      Q. You say there existed the de Laval 23      clinical data, correct?</p> <p>24      A. Yes.</p> <p>25      Q. But he's the inventor, correct?</p>	<p style="text-align: center;">Page 65</p> <p>1       BY MR. FREESE:</p> <p>2       Q. In his own lab is what I mean.</p> <p>3       A. In his own lab, correct.</p> <p>4       Q. Okay. It wasn't done in a factory like 5       TVTO is made today, correct?</p> <p>6       A. It wasn't manufactured by a third party, 7       no.</p> <p>8       Q. And have you reviewed the original launch 9       plan that Ethicon prepared before the launch of the 10      TVTO?</p> <p>11      A. I went through a few papers because I 12      believe it's included in that binder, and I reviewed 13      them probably, I saw it about a year ago.</p> <p>14      Q. Okay, and do you know the original launch 15      plan Ethicon had was that they were going to do 16      clinical studies before the TVTO was launched?</p> <p>17      A. I can't recall specifically they were 18      deciding to do clinical studies on TVTO.</p> <p>19      Q. I'll make that representation to you.</p> <p>20      You don't have any reason to dispute that, do you?</p> <p>21      A. No, no reason to one way or the other.</p> <p>22      Q. And if the original launch plans 23      anticipated Ethicon was going to conduct its own or 24      independent clinical trials before the launch of TVTO, 25      you would have no objection to that, would you?</p>

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<p>1        A. I would have no objection to, to, to 2        that.</p> <p>3        Q. So, because that would be the responsible 4        thing to do, wouldn't it?</p> <p>5           MS. GALLAGHER: Object to form.</p> <p>6        A. No, they'll have their reasons to conduct 7        their studies, and they have their, their own 8        justifications to do whatever trial they may think. I 9        believe that what, what determined that was what their 10      interaction was between what was established between 11      the FDA and Ethicon at that time.</p> <p>12     BY MR. FREESE:</p> <p>13     Q. And that's not really my question, Dr. 14     Sepulveda. My question is, you would agree with me 15     that the plan to do clinical trials before launching a 16     product is a responsible thing to do, that plan itself, 17     theoretically?</p> <p>18     A. In general terms, you could say that 19     doing clinical trials is a good idea, as long as those 20     clinical trials don't put unnecessary subjects to 21     demonstrate things that have already been demonstrated.</p> <p>22     Q. Okay. And that's why you normally want 23     to do clinical trials, right? You want to build a body 24     of science that supports the safety and efficacy of 25     your product, correct?</p>	<p>1        to the launch of the TVT is an Ethicon decision and you 2        have no idea why they didn't do it?</p> <p>3           A. That's going to be an Ethicon decision 4        alone in their interaction with the FDA.</p> <p>5           Q. Should the decision to not do clinical 6        trials ever be based on simply wanting to rush your 7        product to market? Should that ever be a basis not to 8        do a clinical trial?</p> <p>9           MS. GALLAGHER: Object to form.</p> <p>10      A. No, I think that --</p> <p>11      THE WITNESS: Did you get that objection?</p> <p>12      MR. FREESE: She got it, don't worry. 13      She's a big girl. You worry about you, she'll 14      worry about her.</p> <p>15      A. The decision, I believe whenever there 16      are products like this that are innovative, that that 17      decision is going to be again, what I already said, I'm 18      not going to repeat, I mean, I will repeat what I 19      already said, between Ethicon and the FDA, but it's 20      also determined internally by Ethicon, by the different 21      branches that are input in a project, because you may 22      have marketing individuals, you may have sales 23      individuals, you will have scientific individuals, you 24      have engineers, medical liaisons, so you cannot, you 25      cannot just point to one area. I believe that in every</p>
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<p>1        A. Before I continue, I may have said 2        unnecessary subjects. I mean as long as it doesn't put 3        subjects through unnecessary risks. That's what I 4        meant on my answer.</p> <p>5        Q. Yes, sir.</p> <p>6        A. And following with your question?</p> <p>7           MR. FREESE: Would you read back my 8        question? I'm sorry.</p> <p>9           THE COURT REPORTER: And that's why you 10      normally want to do clinical trials, right? 11      You want to build a body of science that 12      supports the safety and efficacy of your 13      product, correct?</p> <p>14      A. Yes, science built up on previous 15      studies.</p> <p>16     BY MR. FREESE:</p> <p>17     Q. And you know that those clinical trials 18      never occurred, correct?</p> <p>19     A. I am not aware of those clinical trials 20      happening.</p> <p>21     Q. And you don't know the reason why they 22      didn't occur, correct?</p> <p>23     A. No, I don't know the reason.</p> <p>24     Q. You said for whatever, whatever reason 25      Ethicon had for not doing those clinical trials prior</p>	<p>1        company, every device company, there's going to an 2        interaction between all these different individuals 3        deciding which, which product gets the studies done. 4        BY MR. FREESE:</p> <p>5           Q. And I'm not quibbling with you about 6        that, Doctor. My question was quite different. Do you 7        agree with me, generally speaking, that, that a 8        responsible medical device company shouldn't forgo 9        clinical trials simply to rush their product onto the 10      market? That's my only question.</p> <p>11      MS. GALLAGHER: Object to form.</p> <p>12      BY MR. FREESE:</p> <p>13      Q. That would not be the responsible thing 14      to do. You agree with that?</p> <p>15      MS. GALLAGHER: Object to form.</p> <p>16      A. It's going to be a decision of the 17      company, but in general, in general, you don't, you 18      don't rush things. You don't rush decisions for 19      surgery, you don't rush decisions to place or take out 20      implants. You don't rush in general any of these 21      decisions.</p> <p>22      BY MR. FREESE:</p> <p>23      Q. And if the decision to forgo clinical 24      trials was simply an economic decision and not based on 25      safety or efficacy, we can agree that that would be</p>

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<p>1 something that Dr. Sepulveda would be critical of?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. If anything that is motivated purely by</p> <p>4 economics, it belongs in a different arena and not</p> <p>5 health care.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Thank you. Doctor, this is sort of a</p> <p>8 question we had started the last hour, but other than</p> <p>9 the life care plan, you said that you prepared the</p> <p>10 entirety of this report. Is that correct?</p> <p>11 A. Yes.</p> <p>12 Q. Did you prepare all the footnotes, too?</p> <p>13 A. Yes, I did, I did, I did prepare those,</p> <p>14 those papers.</p> <p>15 Q. And the reason I was curious is because</p> <p>16 the reports and the footnotes have a remarkable</p> <p>17 similarity to doctors from all over the country that</p> <p>18 work for Ethicon, Dr. Permugia and Dr. Grier and Dr.</p> <p>19 Flynn, I mean, we've got these reports and it's</p> <p>20 remarkable how similar your work is and their work.</p> <p>21 A. I can tell you this, I spent a lot of</p> <p>22 time sitting down and writing. It has, there were a</p> <p>23 few other things that were added to it, there were</p> <p>24 things that have been edited by me on consultation with</p> <p>25 the attorneys, but there's, there's no attorney that is</p>	<p>1 Q. My question is, was any of this report</p> <p>2 cut and pasted from any other report, or was this all</p> <p>3 original work product as of March 23rd, 2016?</p> <p>4 A. No, my report on TVTO is my report on</p> <p>5 TVTO, and if it looks like Christina Permugia's report</p> <p>6 or whoever report, it's what's available there. There</p> <p>7 are no more papers.</p> <p>8 Q. But what I'm saying is this, I won't find</p> <p>9 any, any language in your report that, in any report</p> <p>10 prior to March 23rd, 2016, correct, because this is all</p> <p>11 your work product, so I won't be able to go and find</p> <p>12 any reports prepared by you that looks identical, in</p> <p>13 fact is identical in the entire report, because you</p> <p>14 created this on March 23rd, 2016, correct?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I did not create this on March 23rd.</p> <p>17 This has been written and reviewed over the last year</p> <p>18 and a half, two years.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. When did you start writing your Ramirez</p> <p>21 report?</p> <p>22 A. Over a year ago.</p> <p>23 Q. How many hours do you have in the Ramirez</p> <p>24 matter?</p> <p>25 A. Lot of hours. I mean, this is probably</p>
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<p>1 going to bring out a report that I don't, I don't</p> <p>2 approve.</p> <p>3 Q. I'm not saying you don't approve, but, I</p> <p>4 mean, you sat down and actually put all these footnotes</p> <p>5 in your report?</p> <p>6 A. Yeah, actually the footnotes, I remember</p> <p>7 exactly going through the two papers on the frequency</p> <p>8 of these devices, I remember going through all the</p> <p>9 papers that I have saved over time, and there are other</p> <p>10 papers that were given to me about randomized control</p> <p>11 trials. I wrote this, I wrote this just after, just</p> <p>12 after my, my board, my subspecialty board</p> <p>13 certification.</p> <p>14 Q. Did you cut and paste any of this report</p> <p>15 from another report?</p> <p>16 A. No, I wrote a report, I submitted it, and</p> <p>17 then they came back with extra, extra bibliography, but</p> <p>18 I actually submitted a bibliography.</p> <p>19 Q. Okay, you said they came back with a</p> <p>20 bibliography. You're talking about the footnotes,</p> <p>21 correct?</p> <p>22 A. No, if there's a footnote, if there's a</p> <p>23 citation, there's a citation, I look at these</p> <p>24 citations, and the ones that were submitted, I look at</p> <p>25 them before they came.</p>	<p>1 the case that has taken the longest number of hours.</p> <p>2 Q. And so what is that?</p> <p>3 A. I put it together and I submitted as a</p> <p>4 whole group. Let me tell you, when I started seeing</p> <p>5 this, these cases, I had like four or five cases</p> <p>6 that I was reviewing, and, then, I was asked to do a</p> <p>7 report on Ramirez. There were other cases that did not</p> <p>8 require a report. That's how I know that I, I recall</p> <p>9 sitting weekends and going, and writing this.</p> <p>10 Q. I just haven't seen a Ramirez invoice.</p> <p>11 Have you prepared one?</p> <p>12 A. I believe that there are a few with</p> <p>13 Ramirez numbers.</p> <p>14 Q. But do you have a total Ramirez invoice</p> <p>15 somewhere?</p> <p>16 A. They were submitted last -- well, that's,</p> <p>17 that's, there was a time in which I say no, we want you</p> <p>18 to put for each specific case, and that's when I</p> <p>19 started doing it, a few months ago, that was for</p> <p>20 Ramirez, and I was here with, with Mr. Schnel last week</p> <p>21 and he had, he had those documents.</p> <p>22 Q. Do you have your Ramirez invoice with</p> <p>23 you?</p> <p>24 A. No.</p> <p>25 MS. GALLAGHER: You already have them.</p>

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<p>1 They were here we when started the depo.      2 MR. FREESE: Where are they?      3 THE WITNESS: These are my invoices.      4 MR. JORDAN: There were two exhibits to      5 the letter that Chris Morris sent. One of them      6 you were asking to be blown up. The other is      7 the invoice.      8 MR. FREESE: Right.      9 BY MR. FREESE:      10 Q. These don't break down Ramirez. Are      11 these all Ramirez invoices?      12 A. No, there's a group, it's grouping all      13 the MDL cases, the most recent ones.      14 Q. But you can't tell from these invoices      15 what they're for?      16 A. Yeah, I just group all the hours on      17 there.      18 Q. How many hours do you have in your best      19 judgment on the Ramirez matter?      20 A. I would say over, over a hundred hours.      21 Q. Over a hundred hours on Ramirez?      22 A. Yeah, easily.      23 Q. And that doesn't include your MDL time?      24 A. Nor my MDL.      25 Q. I'm going to mark as the, the cover</p>	<p>1 procedures manuals, there are lab manuals. So this is      2 not, there are people looking over each other's      3 shoulders on research projects. So that's what I call,      4 what I call about the methodology is not only the      5 methodology for the randomized control trial but also      6 the surveillance on it.      7 Q. Who was overlooking Dr. Ulmsten's study,      8 for example, on TVT? Who is looking over his shoulder?      9 A. I don't know who was looking at him.      10 Q. Nobody was. You know that, don't you?      11 A. No, I don't.      12 Q. You realize that nobody was overlooking      13 Ulmsten's studies?      14 A. No, I don't know that.      15 Q. Well, can you name me one person who      16 oversaw what Dr. Ulmsten prepared?      17 A. No, I just don't know who overlooked.      18 Q. Did you ever look at the patient level      19 data for Dr. Ulmsten?      20 A. No.      21 Q. Did you know that Ethicon never even      22 looked at the patient data for TVT studies that Ulmsten      23 did?      24 A. No, I do not know how Ulmsten conducted      25 his research, his research project.</p>
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<p>1 letters from, the payments from Ethicon and the      2 invoices here as Exhibit 7 to your deposition. Okay?      3 A. Okay.      4 (Plaintiff's Exhibit No. 7 was marked for      5 identification.)      6 BY MR. FREESE:      7 Q. When doing your report, Dr. Sepulveda,      8 did you attempt to look and see how many of the authors      9 that you were citing in support of your opinions were      10 paid consultants by Ethicon?      11 A. No.      12 Q. Do you even know how many of these      13 authors you cited are paid consultants of Ethicon?      14 A. No.      15 Q. And were paid consultants at the time      16 they wrote their reports?      17 A. I do not know that.      18 Q. Is that a fact of no consideration of      19 yours, you don't care?      20 A. No, the methodology takes care of      21 whatever bias to be introduced.      22 Q. Well, assuming one knew what the      23 methodology was.      24 A. Yes, there's a methodology, there's      25 auditing on research projects, there's supervision,</p>	<p>1 Q. Am I correct that you have not looked at      2 the patient level data of any of these authors that      3 you're citing in your report?      4 A. No, that's not correct. I have looked      5 at, at these reports and I look at the methodology that      6 they have used.      7 Q. I'm not asking that. I'm talking about,      8 I know you've looked at the methodology. Have you      9 looked at the patient level data that the authors were      10 looking at when they write these reports?      11 A. Define patient level data.      12 Q. The actual data that's collected at the      13 sites for these trials that are being performed.      14 A. How it was collected?      15 Q. Yes, sir. Have you ever gotten the      16 patient level data of any of these studies?      17 A. No, it's not described on the report on      18 any papers, any research papers.      19 Q. You simply take what the authors say and      20 give credit to what they say, assuming that they have      21 given credible, reliable, unbiased results, correct?      22 A. They -- I don't assume. I read the      23 papers, and I read papers that have more accuracy than      24 others in methodology, but that's why there's a section      25 on methodology on each paper.</p>

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<p>1       Q. And you see what the methodology is and 2 then read it, decide you like it, and then cite it?</p> <p>3       A. I decide if I find it accurate, yes.</p> <p>4       Q. You say on page 4 of your report: 5 Overall, there are over 100 randomized control trials 6 that have accumulated and countless more cohort studies 7 on TVT and TVTO. Do you see that?</p> <p>8       A. Yes.</p> <p>9       Q. We can agree, you've lumped TVT and TVTO 10 there in that sense together, have you not?</p> <p>11      A. Yes.</p> <p>12      Q. And we've agreed that they're two 13 different products, correct?</p> <p>14      A. The insertion is different.</p> <p>15      Q. And they're different products?</p> <p>16      A. They are different products because the 17 insertion is different, the needles are different.</p> <p>18      Q. And they have different clearance 19 applications, correct?</p> <p>20      A. They have different clearance 21 applications.</p> <p>22      Q. The TVT was cleared using ProteGen as the 23 predicate product, correct?</p> <p>24      A. Yes.</p> <p>25      Q. So when you say a hundred randomized</p>	<p>1       Q. Why don't you grab that. 2            MR. FREESE: Let's go ahead and mark 3 that, let's slap Exhibit 8 on there.</p> <p>4       BY MR. FREESE:</p> <p>5       Q. And would you tell us what you're looking 6 at there, sir?</p> <p>7       A. I'm looking at the review article from 8 Neurourology and Urodynamics from 2011, and I should 9 have an updated version in my reliance list.</p> <p>10      Q. Okay. Do you know whether or not this 11 was the one that the FDA was looking at in the white 12 paper?</p> <p>13      A. Most likely that's the one that they 14 were, they were looking at.</p> <p>15      Q. Because it's 2011?</p> <p>16      A. Exactly. I don't have the 2016 easily 17 marked in here. I know it's in this pile.</p> <p>18      Q. Let's try to work on this. If you think 19 it's substantially different, then we can maybe find it 20 during a break. Does Exhibit 8 answer your question 21 that I -- does it answer my question? Do you want me 22 to remind you what my question is?</p> <p>23      A. It's how many randomized control trials 24 are on TVTOs?</p> <p>25      Q. Yes, sir.</p>
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<p>1       control trials, we can agree that you didn't mean to 2 suggest to the reader of this that there are over 100 3 randomized control trials of TVTOs. We can agree on 4 that, can we not?</p> <p>5       A. No, of TVT and TVTO.</p> <p>6       Q. Yeah. So, my question to you is, you 7 agree with me that there are not over 100 randomized 8 control trials of TVTO, correct?</p> <p>9       A. That is correct.</p> <p>10      Q. And if you then looked and said I want to 11 know how many -- first of all, do you know how many 12 randomized control trials of TVTO exists?</p> <p>13      A. It's in the Cochrane paper, and I do have 14 an abbreviated portion of the Cochrane and I can refer 15 to it.</p> <p>16      Q. All right, without referring, do you have 17 a judgment how many randomized control trials of TVTO 18 exists?</p> <p>19      A. No, it's in the Cochrane. If I would 20 have asked, if a patient would come and ask me that 21 question I would say I will have to look at the 22 Cochrane review.</p> <p>23      Q. Do you have the Cochrane review with you 24 right now?</p> <p>25      A. Yes.</p>	<p>1       A. Okay, they found 24 trials.</p> <p>2       Q. Where are you looking?</p> <p>3       A. Right here.</p> <p>4       Q. Okay. Are you saying 24 trials address 5 the comparison of transobturator route versus 6 retropubic route?</p> <p>7       A. Yes.</p> <p>8       Q. And then it has those cited. Okay, now, 9 let me ask you further, of these 24, of these 24 10 randomized control studies, they weren't all TVTO 11 studies, were they? They were comparing retropubic 12 versus obturator approach, correct?</p> <p>13      A. Right.</p> <p>14      Q. So, of those 24, not even all 24 of those 15 are dealing with Ethicon's TVTO, is that correct?</p> <p>16      A. No, there's, to do a randomized control 17 trial, if it would be just TVTO, it would be a cohort 18 study. If it's a randomized control trial, you have to 19 have two arms, and with those two arms classically what 20 we have is the retropubic and the, and the TVTO. The 21 biggest study on that is the TOMUS, T-O-M-U-S, the 22 TOMUS trial.</p> <p>23      Q. But my question is, some of these 24 24 studies are not even studying the Ethicon TVTO, they 25 are simply comparing midurethral slings that are using</p>

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<p>1       an obturator approach, it may not even be Ethicon's      2       products being studied, correct?</p> <p>3           A. There are two, they made two comparisons      4       in the Cochrane data review. They made a comparison      5       between transobturator slings and they made a      6       comparison between retropubic and transobturator      7       slings.</p> <p>8           Q. And not necessarily even Ethicon's      9       transobturator slings, correct?</p> <p>10          A. Yeah, they compared different ones.</p> <p>11          Q. And, so, am I correct, you cannot sit      12       here today, Dr. Sepulveda, and tell me how many      13       randomized control studies have been done looking at      14       Ethicon's TVTO? Can you agree that you can't tell me      15       that number?</p> <p>16          A. I can, I can say for certain, without      17       looking into the long version, this is the short      18       version of the Cochrane data review, I can say with      19       accuracy the TOMUS trial.</p> <p>20          Q. One?</p> <p>21          A. Yes.</p> <p>22          Q. Okay. I'll mark Exhibit 9 to your      23       deposition, which is the, do you recognize that as the      24       white paper?</p> <p>25          A. Yes, the FDA Executive Summary.</p>	<p>1           A. Yes, they did have an opinion here.      2           Q. And it says in the first paragraph, under      3       conclusion, safety of mesh used in repair of stress      4       urinary incontinence based on published literature. Do      5       you see that?</p> <p>6           A. Yes.</p> <p>7           Q. Quote, "The Cochrane reviews are limited      8       in the ability to fully evaluate the safety of profile      9       of the surgical mesh used in SUI patients. The main      10       objective of these reviews is to evaluate the      11       effectiveness of the SUI procedures using randomized      12       control trials that have compared a mesh procedure to      13       another approach." Do you see that?</p> <p>14          A. Yes.</p> <p>15          Q. So, the FDA was criticizing the      16       reliability of the Cochrane reviews from a safety      17       standpoint, correct?</p> <p>18          MS. GALLAGHER: Object to form.</p> <p>19          A. That is, that is, that is correct. They      20       disagree with the methodology.</p> <p>21          BY MR. FREESE:</p> <p>22          Q. I accurately read what the FDA said about      23       the Cochrane reviews that you are relying on, correct?</p> <p>24          A. Yes, they, I think that, when you look --</p> <p>25          Q. Hold on. I don't mean to cut you off,</p>
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<p>1           (Plaintiff's Exhibit No. 9 was marked for      2       identification.)</p> <p>3          BY MR. FREESE:</p> <p>4          Q. And you've looked and relied upon this,      5       did you not, in forming your opinions?</p> <p>6          A. I read it and it just allow me to      7       understand. There was no specific cite on my opinion      8       that refers to, to that paper.</p> <p>9          Q. But you actually showed up to your      10       deposition with a highlighted copy of it, did you not?</p> <p>11          A. No, I -- yes, I actually did have a      12       highlight copy, but the only data, the only place in      13       which I refer to the Executive Summary from my report      14       is when I, when I speak about the MAUDE database.</p> <p>15          Q. Let's talk about something different,      16       though. Let me show you Exhibit 9, page 42, of the FDA      17       Executive Paper.</p> <p>18          Now, you've -- and before we get to that,      19       your testimony is you relied on the Cochrane report in      20       forming your opinions today about the safety and      21       efficacy of TVTO, am I correct?</p> <p>22          A. And the Cochrane report and the TOMUS      23       trial and the Tommaselli analysis.</p> <p>24          Q. And the FDA had some comments about the      25       Cochrane review, did it not?</p>	<p>1       but I'm simply asking you, did I accurately read to you      2       just now what the FDA's conclusion was of the Cochrane      3       reviews?</p> <p>4          A. That's what they described, yes.</p> <p>5          Q. If you'll drop down three paragraphs, it      6       says, quote, "The Cochrane reviews did however identify      7       noteworthy differences between mesh procedures and open      8       colposuspension. The risk of perioperative      9       complications favored colposuspension compared to all      10       sling procedures combined, and the risk of voiding      11       dysfunction was similar between colposuspension and the      12       TVT sling." Do you see that?</p> <p>13          A. Yes.</p> <p>14          Q. Did I read that correctly?</p> <p>15          A. You read that. I didn't follow word by      16       word, but you...</p> <p>17          Q. Okay, and that's, that's contrary to the      18       opinion that you've expressed in your report, is it      19       not?</p> <p>20          A. That's, the Cochrane review and the most      21       recent Cochrane review and the TOMUS report are what's      22       used in my report, and there's, I was looking for my      23       2015 Cochrane review, and I just found it.</p> <p>24          Q. Okay, and we'll get to that, but let me      25       finish my question here. You agree with me that the</p>

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<p>1 FDA concluded that the, the Cochrane reviews that you      2 have relied on were noteworthy because they found, in      3 the view of the FDA, that the risks of perioperative      4 complications made mesh less safe compared to      5 colposuspension, correct?</p> <p>6 A. But that's not what it says on the      7 Cochrane review.</p> <p>8 Q. That's what the FDA concluded after      9 reading the Cochrane review, correct?</p> <p>10 A. Yes, but I don't know how they came to      11 that conclusion.</p> <p>12 Q. And you understand, Doctor, what the FDA      13 was doing in 2011 when they prepared this white paper,      14 they were doing a systematic review of all known      15 literature, were they not?</p> <p>16 MS. GALLAGHER: Object to form.</p> <p>17 A. Yes, but that's not what's been published      18 on the summary.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. But what I'm saying, you understand      21 that's what the FDA undertook to do? They undertook to      22 independently collect all known literature on the      23 safety and efficacy of midurethral slings and draw some      24 conclusions from those studies, correct?</p> <p>25 A. If they did a systematic review, I have</p>	<p>1 A. This is not a report of a systematic      2 review. This is an executive summary.</p> <p>3 Q. Have you looked at the systematic review?</p> <p>4 A. I have not seen a systematic review.</p> <p>5 Q. So you're not saying that the systematic      6 review came to any different conclusion than what the      7 summary did, correct?</p> <p>8 A. Well, I have not seen it.</p> <p>9 Q. Okay. But you disagree with the      10 conclusions they reached regarding the Cochrane      11 reviews?</p> <p>12 A. Yes, I do disagree.</p> <p>13 Q. Okay. So, in your view, at least in this      14 respect, Dr. Sepulveda, you would say that the FDA got      15 it wrong in their conclusion regarding what the      16 Cochrane reviews showed about complications from      17 midurethral slings, correct?</p> <p>18 A. Yes, and I base my, my answer on the      19 last, on the last statement on the review article, that      20 says that monofilament tape has significantly higher      21 objective cure rates, and the obturator use wasn't less      22 favorable than retropubic, but only on an 84 to 88      23 percent --</p> <p>24 Q. That's on the cure rates, though.</p> <p>25 A. That's on cure rate.</p>
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<p>1 not seen any publication about the systematic review      2 made by the FDA, because the document that you have in      3 front of you is an executive summary, it's not a      4 systematic review report.</p> <p>5 Q. Would you look at the second paragraph,      6 sir?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Quote, "The FDA's systematic      9 literature review found that the weighted average rates      10 of urinary problems, re-surgery rates and perioperative      11 organ perforations were similar to overall rates      12 presented in published meta-analyses and systematic      13 reviews." Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. They're saying they did a systematic      16 literature review.</p> <p>17 A. Yes, they say that.</p> <p>18 Q. Do you dispute that they did a systematic      19 literature review?</p> <p>20 A. I don't dispute they did it. I just have      21 not seen the document.</p> <p>22 Q. Well, we're looking at the document.</p> <p>23 A. No, this is not a report of a systematic      24 review.</p> <p>25 Q. This is the report of the review.</p>	<p>1 Q. We're talking about complications right      2 now.</p> <p>3 A. Yes, we go through that. However, there      4 were less voiding dysfunction, blood loss, bladder      5 perforation with the obturator route.</p> <p>6 Q. Compared to what?</p> <p>7 A. Compared to colposuspension, pubovaginal      8 slings and retropubic procedures.</p> <p>9 Q. Doctor, let's move up a paragraph here.      In the Cochrane review, minimally-invasive synthetic      11 suburethral sling operation appeared to be as effective      12 as open retropubic colposuspension, correct?</p> <p>13 A. Yes.</p> <p>14 Q. That's talking about efficacy, correct?</p> <p>15 A. Yes.</p> <p>16 Q. But that it had significantly more      17 bladder perforations, correct?</p> <p>18 A. There were more bladder perforations when      19 we compare, when you compare colposuspensions with      20 retropubic slings.</p> <p>21 Q. Doctor, I'm going to mark as Exhibit 10      22 to your deposition the actual appendix to the published      23 review of literature that we've looked at with the FDA.      24 (Plaintiff's Exhibit No. 10 was marked      25 for identification.)</p>

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<p>1 BY MR. FREESE:</p> <p>2 Q. Do you see, you've seen this was actually 3 part of the Executive Summary. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it says the FDA evaluated the 6 peer-reviewed scientific literature to revisit the 7 fundamental question of safety and effectiveness for 8 surgical mesh for POP and SUI, correct?</p> <p>9 A. Yes.</p> <p>10 Q. A systematic literature review was 11 conducted by searching the PubMed database from 12 January, 1996, to April, 2011. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. I won't read you all this, but this says 15 what the FDA actually did, correct?</p> <p>16 A. Yes.</p> <p>17 Q. You have no reason to dispute that they 18 actually did what they say here in Exhibit 10?</p> <p>19 A. I have no reason to dispute that's what 20 they do.</p> <p>21 Q. You just dispute some conclusions they 22 reached?</p> <p>23 A. Yes, I think that the Cochrane review, 24 with all the possible limitations that any study would 25 have, have less limitations than the FDA executive</p>	<p>1 this, the fact that we're looking at an executive 2 summary and the fact that we don't have a systematic 3 review publication just speaks for itself in looking at 4 the overreaching of these conclusions.</p> <p>5 Q. And this goes on to say, quote, "The FDA 6 is concerned that the safety outcomes may not have been 7 comprehensively evaluated by the randomized control 8 trial to date and that the safety of SUI repair with 9 mesh needs to be further considered in evaluating the 10 overall risk-to-benefit profile of these products." Do 11 you see that?</p> <p>12 A. And it was actually further considered.</p> <p>13 Q. Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. Okay, and do you agree with that 16 conclusion?</p> <p>17 A. Yes, it needs to be further considered. 18 I do agree with that. And it was further considered.</p> <p>19 Q. And you agree that the comprehensive 20 review of the RCTs may not have been able to 21 comprehensively capture all of the safety data on the 22 midurethral slings?</p> <p>23 A. No, the RCTs will have established 24 benchmark for safety.</p> <p>25 Q. Well, the conclusion was that they didn't</p>
<p>1 report.</p> <p>2 Q. Even the FDA said the Cochrane review 3 results were only of moderate value, did they not?</p> <p>4 A. Well, there's no standardization of 5 statistical analysis done in concluding that, if they 6 say that.</p> <p>7 Q. Well, they do that say that, don't they? 8 They said that the strength of the Cochrane data is 9 moderate. That's how way they described it, did they 10 not?</p> <p>11 A. Yes, most of it is not moderate.</p> <p>12 Q. And, Doctor, back to page 43 of the 13 executive study.</p> <p>14 A. Yes, I have that right here.</p> <p>15 Q. The FDA said that in the systematic 16 review of the literature conducted by the FDA and based 17 on adverse event reports in the MAUDE database, there's 18 a potential for serious complications with mesh 19 products indicated for SUI repair. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Do you disagree with that?</p> <p>22 A. No, they actually table it, they actually 23 got the frequency, and they actually mentioned the 24 limitations of the MAUDE database. So, that's, I find 25 this, this statement to be overreaching. I think that</p>	<p>1 comprehensively gather the safety data, the RCTs 2 didn't.</p> <p>3 A. That's the executive summary conclusion, 4 but that's not the conclusion of the mesh analysis done 5 by the Cochrane review.</p> <p>6 Q. Again, that's the conclusion of the FDA 7 that you disagree with?</p> <p>8 A. That's what they state and I disagree 9 with it, yes.</p> <p>10 Q. And let me just ask one more question and 11 we'll move on to something else. So, now that we've 12 gone through this discussion here, Dr. Sepulveda, we 13 can agree that the only long-term randomized controlled 14 study of TVTO that you're aware of is the TOMUS study?</p> <p>15 A. No, I am aware of the, of the study done 16 by Cloe in 2013, which is a randomized control trial of 17 the TTV and TOT. I'm also aware of the RCT comparing 18 TTV and TVTO of Aniulene, which is a prospective 19 randomized control trial of TVTO and TTV.</p> <p>20 Q. Over what period of time?</p> <p>21 A. On 264 women.</p> <p>22 Q. For how long?</p> <p>23 A. For -- I cannot answer that question 24 based on this, on what I have.</p> <p>25 Q. So you can't tell if it's a long-term</p>

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1 study or not? 2 A. Well, it's a randomized control trial 3 that looks at safety of the TVTO. I also have, and 4 these are from the new Cochrane review which I found, 5 the one from 2015. I have TVTO being compared to TOT 6 in 2008. 7 Q. How long? 8 A. That's a three month, three month. 9 Q. That's not a long-term study, is it? 10 A. No, there are other longer-term studies. 11 Q. But we can agree that three months is not 12 by anybody's definition a long-term study, correct? 13 A. No, that's a study just about safety. 14 Q. First of all, you're looking at the 2015 15 Cochrane review? 16 A. Yes. 17 Q. Okay. As you sit here today, Doctor, can 18 you tell me how many long-term randomized control 19 trials there are of TVTO -- 20 MS. GALLAGHER: Object to form. 21 BY MR. FREESE: 22 Q. -- whose primary end point is safety? 23 MS. GALLAGHER: Object to form. 24 BY MR. FREESE: 25 Q. How many of those exist?	1 Q. Okay, and in those five-, seven- and 2 ten-year trials, the primary objective was safety. Is 3 that correct? 4 A. Safety. 5 Q. As opposed to efficacy? 6 A. Safety and efficacy is evaluated on both, 7 but now that you mention, the TOMUS trial was safety 8 and efficacy. The Tommaselli medium-term and long-term 9 following midurethral slings, which is a systematic 10 review of meta-analysis as the highest level of 11 evidence, was at 36 months and at 60 months. 12 Q. Okay. So, there's one at 60 months, 13 correct? 14 A. I can, I can continue looking, looking 15 for it, on the different ones, but -- 16 Q. That's fine, and this is not a memory 17 test, and I'm sure your lawyer will be happy to walk 18 you through when we get to the courthouse, but just 19 sitting here right now, you can't name me one study 20 that meets the parameters I just defined, correct? 21 A. Yes, I just, I just mentioned them to 22 you. 23 Q. Which, TOMUS? 24 A. Tommaselli. 25 Q. Tommaselli?
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1 A. I'm just looking through them. 2 Q. Listen to my question. How many of those 3 are long-term studies, what I mean by that, five years 4 or more, how many long-term, controlled, randomized 5 controlled studies of TVTO exist, five years or 6 greater, with the primary end point of safety? How 7 many of those studies? 8 A. Well, I've already gone through three of 9 them, because there's also the Chen study. 10 Q. How long is that? 11 A. This was 12 to 24 months. 12 Q. That's not five years. Doctor, listen to 13 my question. Close the book, you've got to look at me 14 and listen to my question because I think you're 15 getting distracted. Do you know how many randomized 16 controlled studies, long term, by which I mean longer 17 than five years, and whose primary end point was 18 safety, are there dealing with TVTO? 19 A. No, I do not, I do not recall the 20 specific number of them and I know there are trials at 21 five years, seven years, and ten years. 22 Q. Okay. 23 A. There are trials in here, and I have it 24 in my reliance list, but if you're asking me just to 25 recall as a memory test, no, I do not recall that.	1 A. TOMUS trial, which is the best designed 2 and most accurate trial that have ever been done with 3 TTV and TVTO. There's the, there's Chen. 4 Q. Chen was five years or greater? 5 A. That's less. 6 Q. Doctor, we're not getting -- it has to be 7 five years or greater. That's all I'm asking you. How 8 many studies, TVTO, five years or longer, that study 9 the safety of the device? 10 MS. GALLAGHER: Object to form. 11 A. I, I already say that I cannot recall one 12 specific number. 13 BY MR. FREESE: 14 Q. And we can agree that it's way less than 15 a hundred, correct? 16 A. It is less than, than a hundred. 17 Q. It's way less than 24, is it not? 18 A. It might be more than 24 now. 19 Q. As you sit here right now, you're unable 20 to name one. 21 MS. GALLAGHER: Object to form. 22 BY MR. FREESE: 23 Q. Correct? 24 A. I said I cannot recall it. 25 Q. That's fine. That's all I want to know.

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<p>1 Sitting here right now, you cannot name one.</p> <p>2 MS. GALLAGHER: Object to form. He's</p> <p>3 already told you about three.</p> <p>4 MR. FREESE: Counsel.</p> <p>5 A. I already told you the studies that I can</p> <p>6 recall, and I looked at them and I gave you my best</p> <p>7 effort to give you that information.</p> <p>8 BY MR. FREESE:</p> <p>9 Q. All right. And of the TVTO studies that</p> <p>10 you rely on, Doctor, can we agree that none of them</p> <p>11 make a distinction between laser cut versus mechanical</p> <p>12 cut?</p> <p>13 A. Yes, that has been established already.</p> <p>14 Q. Even the doctors who did the study don't</p> <p>15 say whether or not the patients they are studying were</p> <p>16 implanted with laser-cut versus mechanical-cut TVTO,</p> <p>17 correct?</p> <p>18 A. That's correct, there's no definition of</p> <p>19 it.</p> <p>20 Q. And you don't know?</p> <p>21 A. No, I don't know because they did not</p> <p>22 disclose it.</p> <p>23 Q. And if there's in fact a clinically</p> <p>24 significant difference in safety between</p> <p>25 mechanically-cut TVTO and laser-cut TVTO, it won't be</p>	<p>1 slings.</p> <p>2 Q. It goes on to say, quote, "Surgical</p> <p>3 experience made clear that patients treated with TTVT</p> <p>4 had less voiding dysfunction, less wound complications</p> <p>5 and less retention than the historic numbers from</p> <p>6 patients treated with pubovaginal slings, needle</p> <p>7 procedures or retropubic procedures." Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. You don't cite anything for that</p> <p>10 statement, do you?</p> <p>11 A. No, but I --</p> <p>12 Q. Hold on, I'll ask, you don't cite</p> <p>13 anything for that statement?</p> <p>14 A. No, sir, I don't.</p> <p>15 Q. And you're referring to TTVT studies, not</p> <p>16 TVTO studies, correct?</p> <p>17 A. I'm referring to TTVT studies and I'm</p> <p>18 referring to TVTO studies.</p> <p>19 Q. Well, it says TTVT. The sentence says</p> <p>20 that surgical experience made clear that patients</p> <p>21 treated with TTVT. That's a different product than</p> <p>22 TVTO, is it not?</p> <p>23 A. Okay, we keep saying that it's a</p> <p>24 different product. I have the impression that we're</p> <p>25 going to be looking at those different products through</p>
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<p>1 discernable from the studies, will it?</p> <p>2 A. No, it's not discernable from the</p> <p>3 studies. That has not been defined.</p> <p>4 Q. That has what?</p> <p>5 A. That has not been defined.</p> <p>6 Q. Okay. Doctor, would you look at page 14</p> <p>7 of your report?</p> <p>8 A. Yes.</p> <p>9 Q. I just want to ask you real quick, the</p> <p>10 bottom of the first paragraph there, it says no medical</p> <p>11 certification of these complications or diagnostic</p> <p>12 confirmation was required on this report. Do you see</p> <p>13 that?</p> <p>14 A. Yes.</p> <p>15 Q. Would you just -- I don't understand the</p> <p>16 sentence. Can you tell me what that means?</p> <p>17 A. Before we, we saw TTVT and before we saw</p> <p>18 TVTO, before we actually saw midurethral slings, the</p> <p>19 quality of the studies were not, were not strong. We,</p> <p>20 we actually saw the first comparison between</p> <p>21 pubourethral slings and colposuspension in the, in the</p> <p>22 Alba trial published in the New England Journal of</p> <p>23 Medicine, but until then there was a very weak, very,</p> <p>24 very small cohort studies establishing the safety and</p> <p>25 efficacy of Burch colposuspensions and pubovaginal</p>	<p>1 the course of the day. So, do you want me to go</p> <p>2 through the, and I'm sure if you want you'll probably</p> <p>3 ask, but in which regard are we defining those</p> <p>4 differently?</p> <p>5 Q. Well, if I said give me a TTVT and give me</p> <p>6 a TVTO, we would have to have two different boxes,</p> <p>7 wouldn't we?</p> <p>8 A. Yes.</p> <p>9 Q. Okay, because they're two different</p> <p>10 products, correct?</p> <p>11 A. They're two different products in the</p> <p>12 insertion needles, yes.</p> <p>13 Q. They were cleared in a different way?</p> <p>14 A. They were cleared in a different way.</p> <p>15 Q. They had different predicate products?</p> <p>16 A. Yes.</p> <p>17 Q. That's what I mean by they're different</p> <p>18 products. So, when you're citing a TTVT study, that's</p> <p>19 not a study of TVTO, correct?</p> <p>20 A. That's, that's not necessarily a study of</p> <p>21 TVTO. That's a study about the tape.</p> <p>22 Q. That's my point. When you cite a TTVT</p> <p>23 study, it's not a study of TVTO, is it?</p> <p>24 A. No, if I cite a TTVT study, I'm citing</p> <p>25 that. TVTO is TVTO. But, yes, the surgical experience</p>

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<p>1 showed that there were less complications with 2 pubovaginal slings or colposuspensions. 3 Q. Against TTVT? 4 A. Against TTVT, and when TVTO was compared 5 to TTVT, there was less. 6 Q. But your sentence doesn't even mention 7 TVTO, is my only point. 8 A. I did not mention TVTO in that sentence. 9 Q. I mean, is the point you're trying to 10 make, Dr. Sepulveda, that, that you, you like to use 11 TTVT and TVTO studies interchangeably because they 12 involve the same polypropylene mesh? 13 A. Well, there are more similarities than 14 differences. 15 Q. But is it because they use the same mesh? 16 A. No, not necessarily just the same mesh. 17 Q. Well, is that one of the reasons why you 18 use the studies interchangeably? 19 A. Yes, you can actually use one or the 20 other, but I don't even need to refer to TTVT. TVTO has 21 been shown in randomized control trials has been as 22 effective and safer than TTVT. 23 Q. Okay. And, so I guess it would be a fair 24 comparison to compare TTVT Secur to TVTO, right, because 25 it uses the same mesh?</p>	<p>1 BY MR. FREESE: 2 Q. Now, Doctor, am I correct that Prolene 3 mesh is the mesh that's used in all TTVT products, 4 correct? 5 A. Yes. 6 Q. And that's the original old construction 7 Prolene, correct? 8 A. That is the construction of Prolene and, 9 and it's to the same degree of crystallinity that the, 10 of Prolene sutures. 11 Q. I'm not asking about sutures right now, 12 we can talk about that in a minute, but am I correct 13 that the Prolene that is in the TVTO is the same 14 Prolene that was used in Dr. Ulmsten's original TTVT 15 product? 16 A. It's the same construction Prolene. I 17 cannot recall if the exact crystallinity or purity or 18 analysis from Ulmsten. I don't think that he did that. 19 Q. Well, you know that the formulation for 20 Prolene mesh has not changed since the original TTVT 21 produced by Ethicon, correct? And what I'm asking 22 there is, the same mesh that's in TTVT is in TVTO, is in 23 TTVT Abbrevio, TTVT Secur, TTVT Exact. Correct? 24 A. Yes. 25 Q. Okay. And that is a, that is a</p>
<p style="text-align: center;">MS. GALLAGHER: Object to form. A. We're not talking about TTVT Secur now. We can talk about how TTVT Secur, and I have provided testimony before about how TTVT Secur shares similarities with previous generations of TTVTs. BY MR. FREESE: Q. They share the same mesh, do they not? A. They do. Q. As does Abbrevio, that has the same mesh? A. That has the same mesh, right. Q. So, basically, Doctor, on page 14, all these numbers and results of studies you're referring to, these are all TTVT studies, are they not? A. These are TTVT studies. Q. They're not TVTO studies. A. And whatever complication might be reported from TTVT is not going to be higher on TVTO. Q. That's not my question, sir. Everything you're quoting here in your report are TTVT studies, not TVTO studies? A. These are TTVT studies, right. MR. FREESE: Let's take about two minutes. I want to grab some exhibits real quick. (Break from 11:35 a.m. to 11:45 a.m.)</p>	<p style="text-align: center;">small-pore, heavyweight mesh, is it not? A. No, it's not small pore. Q. You think it's a large-pore mesh? A. It is a large pore. Q. And do you think it's a heavyweight mesh? A. It's, in all, of all the applications that I use for midurethra, it's a lightweight mesh. When it's compared to the meshes for prolapse, it's on the heavyweight, it's close to the heavyweight, but not at the level that was the old meshes for hernias. Q. Well, the old hernia mesh is Prolene, correct? A. The old hernia mesh is Prolene. Q. Okay. So, you're agreeing that the Prolene mesh is heavyweight mesh? A. The Prolene mesh is heavyweight, yes. The Prolene that was initially described that we had 20 years ago, that's heavyweight. Q. Well, what is used today is heavyweight mesh, is it not? A. No, the fiber is lightweight. Q. You think the fiber in the TVTO is lightweight? A. Yes. Q. And you think it's large pore?</p>

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<p>1        A. It's large pore.      2        Q. What is the basis for that opinion?      3        A. The large pore is over 75 microns, and      4        the pore size on the mesh for TVT is 1,200 microns.      5        Q. That's an AMI classification that you're      6        using?      7        A. That's on the AMI classification, which      8        we know has its own limitations, but that's the only      9        one that we have to compare the, the large pores with      10      the small pores.      11      Q. The sole basis of you describing Prolene      12      as large pore and lightweight is the AMI      13      classification?      14      A. Yes, on the, on the slings, on the      15      monofilament polypropylene slings, this is one of the      16      largest pores.      17      Q. I'm just asking the sole basis for your      18      opinion on that is the AMI classification?      19      A. No, that's not the sole basis. It's also      20      the fact that it's a large pore, it's over 75 microns,      21      and even when you define larger pores at 200, 300, it's      22      still a lot larger than that.      23      Q. I'm asking you what is your basis for 75      24      microns, other than the AMI classification?      25      A. For the classification of 75 microns, it</p>	<p>1        company, I wouldn't find any internal documents in      2        there saying that Prolene is small pore, heavyweight,      3        would I?      4        A. That would be the basis of the      5        disagreement of the engineers with me. So if there's a      6        document in there, I would like to see it.      7        Q. I'm asking you, Doctor, if I look through      8        here, as you sit here right now, you don't remember      9        them supplying you with any internal documents where      10      the scientists and the researchers at Ethicon      11      repeatedly described their Prolene mesh as heavyweight      12      and small pore? It's not in that binder, is it?      13      A. I don't recall it being in the binder,      14      no.      15      Q. And as you sit here, you don't have any      16      recollection that they supplied you any such documents      17      stating that Prolene is heavyweight and small pore?      18      A. No, I do not.      19      (Plaintiff's Exhibit No. 11 was marked      20      for identification.)      21      BY MR. FREESE:      22      Q. Now, I'm going to show you what I've      23      marked as Exhibit 11 to your deposition. And do you      24      see this chart here, Doctor?      25      A. Yes, I do see it.</p>
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<p>1        is the AMI classification.      2        Q. So, if I say, Doctor, what is the basis      3        of your opinion that Prolene mesh is lightweight and      4        large pore, you would say AMI classification, correct?      5        A. That's, that's the only classification      6        that defines pores.      7        Q. And you have no other basis for that      8        opinion other than that?      9        A. I would not have any, any other on that      10      specific pore size.      11      Q. You understand, Dr. Sepulveda, that the      12      engineers at Ethicon disagree with you, do you not?      13      A. No, I --      14      MS. GALLAGHER: Object to form.      15      A. I cannot base, that's an ambiguous      16      question. I don't know which way they would disagree      17      or what they're saying.      18      BY MR. FREESE:      19      Q. I'm asking you, have you ever seen any      20      internal Ethicon documents describing the Prolene mesh      21      as heavyweight and small pore?      22      A. They -- no, I don't, I don't, I haven't      23      seen anything as small pore.      24      Q. Okay. So, if I looked through your TVTO      25      company documents selected for your review by the</p>	<p>1        Q. Have you ever seen this chart before?      2        A. No.      3        Q. Okay. You see where it has type of mesh,      4        microporous, medium, and macroporous?      5        A. Yes.      6        Q. Can we agree microporous means small pore      7        and macroporous means large pore?      8        A. We can agree on that, yes.      9        Q. All right, and, then, you see where it      10      says hernia?      11      A. Yes.      12      Q. And then you see where it EWH&amp;U? Do you      13      see that?      14      A. Yes.      15      Q. Is that abbreviation for Ethicon Women's      16      Health?      17      A. Yes.      18      Q. And if you look at the first page, you'll      19      see that this document came out of Ethicon's internal      20      files, correct?      21      A. Yes.      22      Q. Because it bears a Bates stamp number      23      from the company, correct?      24      A. That's correct.      25      Q. And under microporous meshes, does the</p>

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<p>1 document list Prolene as a microporous mesh?</p> <p>2 A. This documents list Prolene as</p> <p>3 microporous.</p> <p>4 Q. And it's not just talking about hernia</p> <p>5 mesh, is it?</p> <p>6 A. No, it does mention TVT slings.</p> <p>7 Q. Okay. That includes TVTO, doesn't it?</p> <p>8 A. It just says TVT slings, in plural.</p> <p>9 Q. Which would include the entire family of</p> <p>10 TVT slings, correct?</p> <p>11 MS. GALLAGHER: Object to form.</p> <p>12 A. I cannot testify to that because there's</p> <p>13 no date on this document and there's no specification</p> <p>14 of TVTO or TVT or any other TVTs.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. Well, because TVTs all use the same mesh,</p> <p>17 do they not?</p> <p>18 A. TVTs use the same, and all the products</p> <p>19 use the same mesh.</p> <p>20 Q. So, when it says TVT slings, that</p> <p>21 includes the entire family of TVTs, right, because they</p> <p>22 all use the same, and have always used the same mesh?</p> <p>23 A. Yes, but all it says is TVT slings.</p> <p>24 Q. Right, and they're talking about the mesh</p> <p>25 being microporous. You see that?</p>	<p>1 A. It used a light, lighter weight, yes.</p> <p>2 Q. And the lighter-weight, large-pore</p> <p>3 Ultrapro mesh has been available to the market since at</p> <p>4 least 2003, has it not?</p> <p>5 A. I don't know exactly when. You're</p> <p>6 talking about the Ultrapro?</p> <p>7 Q. Yes, sir.</p> <p>8 A. No, I don't know when that was available</p> <p>9 on the market.</p> <p>10 Q. You know it was years before 2010,</p> <p>11 though?</p> <p>12 A. No, I do not know that.</p> <p>13 Q. You don't know, you have no clue when</p> <p>14 Ultrapro was put on the market?</p> <p>15 A. No.</p> <p>16 Q. Okay. Do you, you, you've implanted</p> <p>17 Prolift Plus Ms, have you not?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. That's a partially-absorbable</p> <p>20 mesh?</p> <p>21 A. That's a partially-absorbable mesh, yes.</p> <p>22 Q. And you know you were implanting that</p> <p>23 years before 2010, correct?</p> <p>24 A. I did not use Ultrapro.</p> <p>25 Q. Okay. When did you use Ultrapro?</p>
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<p>1 A. Yes.</p> <p>2 Q. And you've never seen this document</p> <p>3 before, have you?</p> <p>4 A. No.</p> <p>5 Q. The lawyers didn't show it to you, did</p> <p>6 they?</p> <p>7 A. I, I just, I just haven't seen it.</p> <p>8 Q. You disagree with that description, I</p> <p>9 gather?</p> <p>10 A. I do.</p> <p>11 Q. Okay. And it says macroporous, and it</p> <p>12 has Vapro, Vapro II, Ultrapro. Do you know what those</p> <p>13 are?</p> <p>14 A. Yes.</p> <p>15 Q. Those are, Ultrapro is the mesh that was</p> <p>16 used in Gynemesh Plus M and Prolift Plus M, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And you're familiar with those products,</p> <p>19 correct?</p> <p>20 A. I am familiar with them.</p> <p>21 Q. You implanted Prolift repeatedly, did you</p> <p>22 not?</p> <p>23 A. I did.</p> <p>24 Q. And that used a lighter-weight,</p> <p>25 large-pore mesh, did it not?</p>	<p>1 A. I used the polyglecaprone polypropylene</p> <p>2 mesh when it became available with Gynemesh. I'm</p> <p>3 sorry, with Prolift Plus M.</p> <p>4 Q. What mesh was Prolift Plus M?</p> <p>5 A. Polyglecaprone polypropylene.</p> <p>6 Q. Okay. That's partially absorbable, is it</p> <p>7 not?</p> <p>8 A. That's partially absorbable.</p> <p>9 Q. It's a lighter-weight mesh, is it not,</p> <p>10 than Prolene?</p> <p>11 A. It's heavier when it's implanted. It</p> <p>12 just gets lighter as the polyglecaprone component is</p> <p>13 absorbed.</p> <p>14 Q. Because it absorbs and becomes a lighter</p> <p>15 mesh, correct?</p> <p>16 A. Yes, it's lighter when you, when you take</p> <p>17 it out, and you measure after the polyglecaprone</p> <p>18 component, it's lighter.</p> <p>19 Q. And the pores on the Ultrapro are</p> <p>20 considerably larger than they are in the Prolene, are</p> <p>21 they not?</p> <p>22 A. I don't know exactly in the product of</p> <p>23 Ultrapro, and I don't want to infer from one product to</p> <p>24 another on these, on these devices.</p> <p>25 Q. You've implanted all of them, Prolifts,</p>

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<p>1     TVT slings, correct?</p> <p>2     A. Yes.</p> <p>3     Q. And you know that they have considerably</p> <p>4     larger pores in the Ultrapro than the TVT Prolift.</p> <p>5     A. You're asking about Ultrapro, but if you</p> <p>6     ask me about Prolift Plus M, we'll have a better</p> <p>7     understanding of it. I just don't want to give</p> <p>8     testimony on Ultrapro that is used for hernia.</p> <p>9     Q. Okay. I see the distinction. Let me</p> <p>10    clear it up. You know that Ultrapro mesh is used in</p> <p>11    Prolift Plus M?</p> <p>12    A. It is polyglecaprone polypropylene, yes.</p> <p>13    Q. And you've used it?</p> <p>14    A. I have used it, yes.</p> <p>15    Q. And it has considerably larger pores than</p> <p>16    Prolene mesh, correct?</p> <p>17    A. It has a larger pore than Prolene mesh,</p> <p>18    yes.</p> <p>19    Q. And all of these products that are being</p> <p>20    discussed here, these are either pelvic floor prolapse</p> <p>21    products or stress urinary incontinence products,</p> <p>22    correct?</p> <p>23    A. Well, Gynemesh Plus M and Prolift Plus M</p> <p>24    are for prolapse. TVT slings are for incontinence.</p> <p>25    Q. And Prosima is for prolapse, correct?</p>	<p>1     A. Yeah, the, the reports for -- the</p> <p>2     definitions for microporous and macroporous are very</p> <p>3     clear.</p> <p>4     Q. Now, do you know Joerg Holste?</p> <p>5     A. No.</p> <p>6     Q. Have you ever heard of him before?</p> <p>7     A. No.</p> <p>8     Q. I'm the first, me uttering his name is</p> <p>9     the first time you ever heard it?</p> <p>10    A. Yes.</p> <p>11    Q. Okay.</p> <p>12    A. I may have heard his name from, or seen</p> <p>13    it, but I don't, maybe once, I don't know, I don't</p> <p>14    recall this, this person.</p> <p>15    Q. Okay, did you know that you put down on</p> <p>16    your reliance list that you read his deposition and</p> <p>17    relied on it in forming your report in this case?</p> <p>18    A. I read that over a year, a year ago, yes.</p> <p>19    Q. Well, you just signed this last week,</p> <p>20    didn't you, sir?</p> <p>21    A. Well, you just asked me if I knew him. I</p> <p>22    don't know him.</p> <p>23    Q. I asked you do you know who he is. You</p> <p>24    don't even know who he is?</p> <p>25    A. I don't know who he is.</p>
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<p>1     A. Prosima is for prolapse as well as</p> <p>2     Prolene and Gynemesh.</p> <p>3     Q. That's what I'm saying, every one of the</p> <p>4     products listed on this exhibit are products for the</p> <p>5     treatment of either pelvic organ prolapse or stress</p> <p>6     urinary incontinence, correct?</p> <p>7     A. On the column, on the side, under EWH&amp;U,</p> <p>8     yes.</p> <p>9     Q. And you would disagree with that</p> <p>10    document?</p> <p>11    A. On what part would I disagree?</p> <p>12    Q. That, describing TVT slings as being</p> <p>13    microporous?</p> <p>14    A. Yeah, I do disagree with that.</p> <p>15    Q. Do you agree that Gynemesh Plus M and</p> <p>16    Prolift Plus M is macroporous, do you agree with that</p> <p>17    portion?</p> <p>18    A. They're all macroporous.</p> <p>19    Q. You would put every one of these products</p> <p>20    in the macroporous category, not the three separate</p> <p>21    categories that Ethicon internally did, correct?</p> <p>22    A. Yes, that's, they're all macroporous</p> <p>23    products.</p> <p>24    Q. Even if Ethicon describes them as three</p> <p>25    different weights?</p>	<p>1     Q. Okay, that's fine. And three days ago</p> <p>2     you supplemented your reliance list, and Dr. Holste is</p> <p>3     listed as one of the depositions you read and relied on</p> <p>4     in forming your opinions, correct?</p> <p>5     A. Yeah, I read it a very long time ago.</p> <p>6     Q. Okay. But he's on your reliance list,</p> <p>7     correct?</p> <p>8     A. He's on my reliance list, yes.</p> <p>9     (Plaintiff's Exhibit No. 12 was marked</p> <p>10    for identification.)</p> <p>11    BY MR. FREESE:</p> <p>12    Q. Let me show you Exhibit 12 to your</p> <p>13    deposition, sir, and show you a question and answer</p> <p>14    that Dr. Holste was asked at his deposition, the</p> <p>15    deposition that you got on your reliance list. He</p> <p>16    says, the question is, quote, "And Prolene</p> <p>17    old-construction mesh at 100 to 110 grams per meter</p> <p>18    squared is considered a heavyweight mesh, correct?"</p> <p>19     Answer: "Correct."</p> <p>20     Do you see that?</p> <p>21     A. Yes.</p> <p>22     Q. And you disagree with Dr. Holste?</p> <p>23     A. No, 110 grams per square meter, that's</p> <p>24     heavy.</p> <p>25     Q. That's a heavyweight?</p>

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<p>1           A. That's the heaviest I've ever seen, by 2         the way.</p> <p>3           Q. Did you know that Prolene was 100 to 110 4         grams per meter squared? Did you know that was the 5         weight of Prolene?</p> <p>6           A. No, that's old-construction Prolene.</p> <p>7           Q. That's old-construction Prolene. Do you 8         know that's the same mesh that TVTs are made out of?</p> <p>9           A. No, I don't know that.</p> <p>10          Q. Okay, you don't believe that?</p> <p>11          A. I don't believe that.</p> <p>12          Q. Okay. But you would agree that if the 13         mesh is 100 to 110 grams per meter squared, that's a 14         heavyweight mesh under anybody's definition, correct?</p> <p>15          A. That's the heaviest I've ever seen.</p> <p>16          Q. Okay. And you think that's a different 17         mesh than what's used in TVT?</p> <p>18          A. Yes.</p> <p>19          Q. And you've never seen, that you recall, 20         this deposition testimony I just showed you, right?</p> <p>21          MS. GALLAGHER: Object to form.</p> <p>22          A. I, I read about his deposition, I read 23         his, may have read his deposition once.</p> <p>24          BY MR. FREESE:</p> <p>25          Q. Which you said you relied on in your</p>	<p>1           Q. Now, do you know who Brigitte Hellhammer 2         is?</p> <p>3           A. No.</p> <p>4           Q. Have you ever heard that name before?</p> <p>5           A. I don't recall that one. (Plaintiff's Exhibit No. 14 was marked for identification.)</p> <p>8          BY MR. FREESE:</p> <p>9          Q. All right. Let me show you what I've 10         marked as Exhibit 14 to your deposition, sir.</p> <p>11          MS. GALLAGHER: Did we skip 13?</p> <p>12          MR. FREESE: I did. I'm going to come 13         back to 13.</p> <p>14          BY MR. FREESE:</p> <p>15          Q. You see Dr. Hellhammer here? Do you see 16         that, sir?</p> <p>17          A. Okay, yeah, I see her name here. Brigitte Hellhammer.</p> <p>19          Q. And you testified that Prolene was, was a 20         large-pore mesh, correct?</p> <p>21          A. Yes.</p> <p>22          Q. All right. And you see that in 23         September, 2013, Dr. Hellhammer's deposition was taken, 24         just like we're here taking yours, and she's under oath, and she was asked the question: "And you agree</p>
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<p>1         reliance materials, correct?</p> <p>2           A. Right.</p> <p>3           Q. This is the guy who you said you relied 4         on, correct?</p> <p>5           A. No, this is the guy that you're showing 6         me a picture right now that you tell me that I have 7         relied on.</p> <p>8           Q. No, sir, I'm showing you your reliance 9         list. Joerg Holste. You see that? Here's a nice 10        picture of Dr. Holste. Deposition testimony of Dr. 11        Holste taken July 29th, 2013. Do you see that?</p> <p>12          A. Yes.</p> <p>13          Q. Same guy, right?</p> <p>14          A. Yes.</p> <p>15          Q. Okay.</p> <p>16          A. I don't know if that's the same guy.</p> <p>17          Q. Well, if it's not, I'm sure Ms. Gallagher 18         is going to let me know very quickly, but if that's the 19         same guy, we can at least agree that you don't agree 20         with Dr. Holste saying that Prolene mesh is 21         heavyweight, but you agree that at 110 grams per meter 22         squared is heavyweight mesh?</p> <p>23          MS. GALLAGHER: Object to form.</p> <p>24          A. Yes, that's the heaviest I've ever seen.</p> <p>25          BY MR. FREESE:</p>	<p>1         that Prolene mesh that was used in TVT was small-pore 2         mesh, correct?" And what was her answer, sir?</p> <p>3           A. She answered yes.</p> <p>4           Q. And do you recall ever seeing this 5         deposition question and answer before today?</p> <p>6           A. No. No, I certainly do not recall this 7         one specifically.</p> <p>8           Q. Do you realize that she also appears on 9         your reliance list?</p> <p>10          A. Yes.</p> <p>11          Q. That you relied specifically on her 12         deposition that was taken on 9/11 and 9/12 of 2013. Do 13         you see that?</p> <p>14          A. Oh, she's in the whole list of those 15         documents. I did not, I do not rely for my opinion on 16         whatever she says.</p> <p>17          Q. I'm not asking you that, sir. I'm asking 18         you, you put on your reliance list that you read and 19         relied on Dr. Hellhammer, and I've just shown you a 20         question and answer where she said Prolene mesh was a 21         small-pore mesh. Do you see that?</p> <p>22          MS. GALLAGHER: Object to form.</p> <p>23          A. But I disagree with her.</p> <p>24          BY MR. FREESE:</p> <p>25          Q. I understand that. That was my next</p>

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<p>1 question. You disagree with her, correct?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Do you know who she is?</p> <p>4 A. No.</p> <p>5 Q. Do you know what her background is?</p> <p>6 A. No.</p> <p>7 Q. Do you know whether or not you're more</p> <p>8 familiar with the pore size of mesh than Dr. Hellhammer</p> <p>9 is?</p> <p>10 A. I know what I know. I don't know what</p> <p>11 she knows.</p> <p>12 Q. Do you know she's a German employee of</p> <p>13 Ethicon?</p> <p>14 A. No.</p> <p>15 Q. Did you know that Dr. Holste was a</p> <p>16 materials expert for Ethicon in Germany?</p> <p>17 A. No, I don't, I don't know that.</p> <p>18 Q. And you simply disagree with her</p> <p>19 conclusion, is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. All right. Now, let me show you what I'm</p> <p>22 marking as Exhibit 13 to your deposition.</p> <p>23 (Plaintiff's Exhibit No. 13 was marked</p> <p>24 for identification.)</p> <p>25 BY MR. FREESE:</p>	<p>1 A. Yes.</p> <p>2 Q. That's heavyweight mesh, is it not?</p> <p>3 A. That is a heavyweight, yes.</p> <p>4 Q. And you just described, you told me</p> <p>5 anything that would be 105 to 110 grams would be the</p> <p>6 heaviest mesh you can recall, correct?</p> <p>7 A. A hundred ten is the largest that I have</p> <p>8 seen.</p> <p>9 Q. And if we look at Prolene mesh, that is</p> <p>10 the mesh used in TVT, is it not?</p> <p>11 A. The Prolene mesh are used on TVT may be</p> <p>12 lower than that.</p> <p>13 Q. Well, do you have anything that says it</p> <p>14 is?</p> <p>15 A. Yes, actually, yes, I think I have a</p> <p>16 paper that actually says that.</p> <p>17 Q. Well, I'm showing you a paper that you</p> <p>18 relied on to put in your, your reliance list that says</p> <p>19 the weight of the Prolene mesh is 105 grams per meter</p> <p>20 squared. You have no reason to dispute that, do you?</p> <p>21 A. Yeah, but this is a, this is a paper</p> <p>22 about hernia.</p> <p>23 Q. It's dealing with Prolene mesh, sir. You</p> <p>24 understand that, do you not?</p> <p>25 A. Yeah, I do understand that.</p>
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<p>1 Q. I think we went backwards. But, you see</p> <p>2 this article, sir?</p> <p>3 A. Yes.</p> <p>4 Q. The argument for lightweight</p> <p>5 polypropylene mesh in hernia repair?</p> <p>6 A. I see this article, yes.</p> <p>7 Q. By Dr. Cobb and Dr. Kercher and Dr.</p> <p>8 Heniford?</p> <p>9 A. Yes.</p> <p>10 Q. Have you seen this article before, sir?</p> <p>11 A. I may have seen it. I can not remember.</p> <p>12 Q. Did you realize it's on your reliance</p> <p>13 list?</p> <p>14 A. It's probably on my reliance list, yes.</p> <p>15 Q. Okay. And did you read it?</p> <p>16 A. Yes, actually, I read that sometime ago,</p> <p>17 even before it was, it was a matter of litigation.</p> <p>18 Q. Okay, turn to the second page. It says</p> <p>19 concept of lightweight mesh. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And you see that there's a table of</p> <p>22 polypropylene meshes with different densities?</p> <p>23 A. Yes.</p> <p>24 Q. And you see that Dr. Cobb has reported</p> <p>25 that Prolene mesh is 105 grams per meter squared?</p>	<p>1 Q. And it's reporting Prolene mesh at 105</p> <p>2 grams per meter squared, correct?</p> <p>3 A. Yes, it is reporting that.</p> <p>4 Q. And you said it's dealing with hernia,</p> <p>5 but you cited it yourself in your own report, did you</p> <p>6 not?</p> <p>7 A. It's not specifically for this hernias.</p> <p>8 I do not cite in this report for Jennifer Ramirez, I do</p> <p>9 not cite this specific report.</p> <p>10 Q. Yes, you did. You don't think that you</p> <p>11 cited this article in your report?</p> <p>12 A. Yeah, I want to see exactly where, where</p> <p>13 is it.</p> <p>14 Q. I'm talking about in your reliance list.</p> <p>15 A. Oh, okay, you're talking about reliance</p> <p>16 list, yes, it is in the reliance list.</p> <p>17 Q. Okay, because you've given us a 100-page</p> <p>18 reliance list that says these are the materials that</p> <p>19 Jaime Sepulveda has relied on in forming my opinions,</p> <p>20 correct?</p> <p>21 A. Yes, but --</p> <p>22 MS. GALLAGHER: Form.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. And that includes this article, does it</p> <p>25 not?</p>

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<p>1        A. Yes, but the definition of relied doesn't      2 mean that I'm using it for my, for my, to, to      3 substantiate my, my opinion. I, I do read papers that      4 I exclude as I, as I'm reading them.</p> <p>5        Q. You didn't exclude this paper from your      6 reliance list, did you? You included it.</p> <p>7        A. Yes, it's included in there, but it's not      8 in my report.</p> <p>9        Q. And, in fact, Prolene mesh is even      10 heavier than Marlex, is it not?</p> <p>11      A. Yes, it shows that.</p> <p>12      Q. And you know what Marlex is, do you not?</p> <p>13      A. I know Marlex, yes.</p> <p>14      Q. It's polypropylene also, is it not?</p> <p>15      A. Yes, but it's not a multifilament.</p> <p>16      Q. You think Marlex is a multifilament?</p> <p>17      A. Yes, it's just a multifilament.</p> <p>18      Q. Okay, and what product is Marlex used in?</p> <p>19      A. The pore size is a lot smaller because      20 it's a multifilament.</p> <p>21      Q. Okay, where did you get that from?</p> <p>22      A. From what I have read.</p> <p>23      Q. Okay, can you cite me any --</p> <p>24      A. That's Mersilene.</p> <p>25      Q. You think Marlex is Mersilene?</p>	<p>1        Q. And that is about one-quarter the weight      2 of Prolene, is that correct?</p> <p>3        A. That's about a quarter, yes, according to      4 this table, yes.</p> <p>5        Q. Now, Doctor, would you look at, down at      6 the first column on the concept of lightweight mesh,      7 you see it there?</p> <p>8        A. Yes.</p> <p>9        Q. See where it says Marlex?</p> <p>10      A. Yes.</p> <p>11      Q. Marlex, paren, C.R. Bard. Do you know      12 who C.R. Bard is?</p> <p>13      A. That's a company, yes.</p> <p>14      Q. That makes slings, correct?</p> <p>15      A. They, they do make slings.</p> <p>16      Q. It says Marlex is a standard monofilament      17 heavyweight polypropylene mesh. Do you see that?</p> <p>18      A. Is a monofilament, yes.</p> <p>19      Q. So, you want to retract your last answer      20 about Marlex?</p> <p>21      A. No, because it's a, with the pore size      22 that it has, it's a, that's a multifilament.</p> <p>23      Q. Well, according to the Cobb article, it's      24 a standard monofilament. Do you disagree, then, that      25 Marlex is a standard monofilament heavyweight</p>
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<p>1        A. Yes.</p> <p>2        Q. Okay. Marlex is polypropylene, Dr.      3 Sepulveda.</p> <p>4        A. Yes, so, it's a Mersilene.</p> <p>5        Q. And you think that, that Marlex is a      6 multifilament?</p> <p>7        A. Yes.</p> <p>8        Q. And what is your support for that?</p> <p>9        A. That I have read about Marlex before.</p> <p>10      Q. Okay. Do you know that it's used in, in      11 Boston Scientific and AMS slings?</p> <p>12      A. I never used a Boston Scientific.</p> <p>13      Q. You've used AMS slings before, have you      14 not?</p> <p>15      A. I used AMS slings, but they were not made      16 of Marlex.</p> <p>17      Q. Okay. Who do you think makes the      18 polypropylene for AMS and Bard and Boston Scientific      19 slings?</p> <p>20      A. I don't know.</p> <p>21      Q. You don't think it's Marlex, though?</p> <p>22      A. No, it's not Marlex.</p> <p>23      Q. And you see where it says the weight of      24 Ultrapro is 28 grams per meter squared?</p> <p>25      A. Yes.</p>	<p>1        polypropylene mesh?</p> <p>2        A. Yes, the pore size in Marlex is a small,      3 is a small size and it behaves like a multifilament.      4 The weave, the weave -- I'm sorry, the knit is a      5 multifilament.</p> <p>6        Q. This article says it's a monofilament,      7 not a multifilament. Do you see that?</p> <p>8        A. That's what this article says.</p> <p>9        Q. And you disagree with the Cobb article on      10 that?</p> <p>11      A. Yes, the fibers are too close.</p> <p>12      Q. It goes on to say that it contains 95      13 grams per meter squared of polypropylene, is porous but      14 has very small inter -- I always have a hard time      15 pronouncing that.</p> <p>16      A. Interstices.</p> <p>17      Q. Would you tell us what that is, please?</p> <p>18      A. It's the space in between the fibers.</p> <p>19      Q. It says it's extremely strong. It says      20 several comparable formulations of heavyweight      21 polypropylene are available with a similar      22 polypropylene content as Marlex, including Prolene,      23 Ethicon, Inc., Somerville, New Jersey. Do you see      24 that?</p> <p>25      A. Yes, that's what it says, yes.</p>

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<p>1       Q. That's saying that, that from a weight      2 standpoint, that Prolene and Marlex are both      3 monofilament heavyweight meshes, correct?</p> <p>4       A. Marlex is lighter, but the configuration      5 of Marlex makes it as a multifilament.</p> <p>6       Q. That's not my question. According to Dr.      7 Cobb, both Prolene and Marlex are heavyweight      8 polypropylene meshes, correct?</p> <p>9       A. According to, to Dr. Cobb, it's, it's      10 porous but has very small interstices, which is what      11 I've been referring to.</p> <p>12      Q. And it says several comparable      13 formulations of heavyweight polypropylene are available      14 with similar polypropylene content as Marlex, including      15 Prolene, correct?</p> <p>16      A. Yes, including Prolene.</p> <p>17      Q. Do you agree or disagree with that      18 statement?</p> <p>19      A. Well, it says that there are several,      20 several heavyweights. That's what he is explaining.</p> <p>21      Q. He says Marlex and Prolene are both      22 heavyweight polypropylene mesh.</p> <p>23      A. That's what he says, that it's      24 heavyweight, yes.</p> <p>25      Q. And you disagree with that?</p>	<p>1       Q. Okay, you're saying the use of the      2 plastic sheath reduces the deformation of the mesh when      3 it's being implanted?</p> <p>4       A. Yes, and the, when the IFU explains that      5 there is, not to put it too tight, that's how you      6 prevent deformation.</p> <p>7       Q. Deformation of the, of the mesh is an      8 unwanted result, is it not?</p> <p>9       A. No, when I talk about deformation, I'm      10 talking about biomechanical deformation. Deformation      11 in biomechanics is different from deformation that we      12 see normally, and deformation has to do with the change      13 on the dimensions of the tape.</p> <p>14      Q. I'm not, I'm not quibbling with you about      15 that, but we can agree that deformation generally is an      16 unwanted result of the mesh, either mechanically or in      17 vivo, or any process you don't want the mesh to deform,      18 correct?</p> <p>19      A. Well, in any viscoelastic that is used      20 will have a degree of deformation, which is that it      21 changes in shape. Any, any viscoelastic, any      22 viscoelastic substance will go through deformation,      23 your skin, your ligaments, and any implant that you may      24 place.</p> <p>25      Q. Look at page 19, sir. The last</p>
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<p>1       A. Yeah, the, the mesh in use of slings is      2 not a heavyweight mesh.</p> <p>3       Q. Well, if it's 105 grams per meter      4 squared, you would agree that it's heavyweight, right?</p> <p>5       A. Yes, that's heavy.</p> <p>6       Q. All right, and if I proved to you at      7 trial that Prolene mesh used in TVT and TVTO and TVT      8 Abbrevio and TVT Secur is 105 grams per meter squared,      9 we would all agree then that that's heavyweight mesh?</p> <p>10      A. At 105 or 110, what I have shown you, you      11 have shown me, I will have no other choice but to agree      12 with you.</p> <p>13      Q. Thank you, sir. Dr. Sepulveda, if you      14 would look at page 18 of your report. You see where,      15 in the first full paragraph, you say, when placed per      16 the IFU, the risk of deformation of the tape is      17 reduced?</p> <p>18      A. When placed per the IFU, the risk of      19 deformation of the tape is reduced.</p> <p>20      Q. You see that?</p> <p>21      A. Yes.</p> <p>22      Q. And my only question is, is reduced      23 compared to what?</p> <p>24      A. It's to, to the deformation that you      25 would have if you put it without plastic sheaths.</p>	<p>1       paragraph, where it starts with complications.</p> <p>2       A. Yes.</p> <p>3       Q. You see where it says the transobturator      4 approach showed a higher frequency of early      5 postoperative pain as the insertion needle went through      6 the superficial muscles of the leg? Do you see that?</p> <p>7       A. Yes.</p> <p>8       Q. What are you defining as superficial      9 muscles of the leg?</p> <p>10      A. Specifically, the adductor magnus.</p> <p>11      Q. The adductor magnus muscles?</p> <p>12      A. Yes.</p> <p>13      Q. Okay. And you go on, this complication      14 is most often transient and managed with medication.      15 What does it mean, most often transient?</p> <p>16      A. It's of short duration.</p> <p>17      Q. Okay. So, more than half the time it's      18 of short duration?</p> <p>19      A. Yes.</p> <p>20      Q. All right, and it could also be a      21 long-term pain and a long-term complication, can it      22 not?</p> <p>23      A. I think that was defined as something      24 that is extremely rare.</p> <p>25      Q. And how do you define extremely rare?</p>

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<p>1        A. It's when, when you look at the, at the      2 leg pain in the cohorts that are five years and seven      3 years, there's, there's a very low rate of long-term      4 pain. Actually, it's not, it's not described in many      5 of these papers, it's not described.</p> <p>6        Q. Look on page 20. You see the paragraph      7 that begins it became evident that specialized      8 knowledge of the obturator site and the anatomy and      9 relationship of the vascular, muscular and nerve      10 studies were required for a reproducible and safe      11 obturator procedure, do you see that?</p> <p>12      A. Yes.</p> <p>13      Q. Where is that in the IFU? Where does it      14 say that, that you need special knowledge of the      15 anatomy in order to safely implant an obturator device?</p> <p>16      A. It's part, knowing the anatomy is part of      17 what is required from a physician as stated on the IFU.      18 It's physicians that are familiarized with continence      19 procedures.</p> <p>20      Q. But you're saying specialized knowledge      21 over and above the average physician is necessary?</p> <p>22      A. No, specialized knowledge is knowing      23 exactly about the obturator space.</p> <p>24      Q. But specialized knowledge compared to      25 who?</p>	<p>1        bundle.</p> <p>2        Q. How far is a properly-placed TVTO from a      3 pudendal nerve bundle?</p> <p>4        A. It's at least four centimeters.</p> <p>5        Q. You go on to say, on the next page, the      6 proximity to the obturator neurovascular bundle was      7 most frequently a failure to orient the device from 45      8 degrees to 90 degrees as specified by the IFU.</p> <p>9        A. Yeah, there are three, three factors that      10 have been validated as the variations in the placement      11 of a transobturator sling from the inside out. The      12 first factor is the dorsal lithotomy position, which is      13 addressed by the IFU. The second factor is the      14 insertion, or the depth of the insertion of the needle      15 in the periurethral space, and the, the third factor is      16 a full rotation of the wrist with rotation from 45 to      17 90 degrees when the needle is exteriorized. Those      18 three factors determine how close the tape is going to,      19 is going to be in relation to the neurovascular bundle.</p> <p>20      Q. All right, and if it's not done that way,      21 then you can get an obturator nerve injury?</p> <p>22      A. Yes, if you, if you actually dissect a      23 cadaver and you insert it wrong to see where you get      24 out, you can, you can get there.</p> <p>25      Q. You say you can get there, you can get</p>
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<p>1        A. Compared to what you do normally. I'm      2 going to explain that.</p> <p>3        Q. What I want to know is, are you talking      4 about special knowledge within a subgroup of doctors,      5 or simply you have to have more anatomical knowledge      6 than, say, a court reporter or a lawyer?</p> <p>7        A. No, you, you need, even if do you      8 continence procedures, you're going to, you're needing      9 to know the anatomy of the obturator space.</p> <p>10      Q. Is it anywhere in the IFU that you have      11 to have specialized knowledge of the anatomy in order      12 to safely reproduce an obturator procedure?</p> <p>13      A. It just says that physicians should be      14 trained on the procedure.</p> <p>15      Q. Okay. And it says that the, the      16 obturator neurovascular bundle 1.2 to 1.5 centimeters      17 for TVTO, that's the distance between where a      18 properly-placed TVTO should go in the obturator nerves?</p> <p>19      A. That's what has been, has been measured.</p> <p>20      Q. Okay. So, in other words, if a TVTO is      21 properly placed, it should be 1.2 to 1.5 centimeters      22 from the obturator nerve bundle?</p> <p>23      A. Yes, there's a safe area for placement of      24 a transobturator sling that is about 2.5 centimeters,      25 1.5 to 2.5 centimeters from the obturator neurovascular</p>	<p>1        there and you can damage or injure an obturator nerve?</p> <p>2        A. You can, you can injure an obturator      3 nerve as has been shown in some, some reports.</p> <p>4        Q. Now, Doctor, you discussed --</p> <p>5        A. And when I say as it has been shown in      6 some reports is that anatomically, it has been      7 described that when you don't insert the device      8 properly, you can injure the neurovascular bundle.</p> <p>9        Q. All right. Have you ever seen a report      10 of an obturator nerve injury from the explant of a TVT?</p> <p>11      A. No.</p> <p>12      Q. As you sit here today, there's no      13 literature that we can find that, that you've seen      14 that's been reported where any patient has suffered an      15 obturator nerve injury from the revision or removal of      16 a mesh sling?</p> <p>17      A. No, I have not seen an obturator nerve      18 injury from the removal of a, a sling.</p> <p>19      Q. And what about the pudendal nerve injury,      20 have you ever seen a report of a patient getting a      21 pudendal nerve injury from the removal or revision of a      22 sling?</p> <p>23      A. I have not seen that, that report.</p> <p>24      Q. Ever?</p> <p>25      A. It has not been published.</p>

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<p>1           Q. Have you in your practice come across 2           that?</p> <p>3           A. No, I have not seen that in my practice.</p> <p>4           Q. You say in 2013 that the -- well, strike 5           that.</p> <p>6           You document 2008, 2011, 2013 FDA Public 7           Health Notifications regarding synthetic mesh?</p> <p>8           A. Well, for this one it's the 2008 because 9           the sling wasn't implanted in 2010 in this case.</p> <p>10          Q. Right. So, the only, the only FDA notice 11         that Dr. Reyes could have been aware of is the 2008, 12         correct?</p> <p>13          A. That is correct.</p> <p>14          Q. Because the 2011, 2013, hadn't even come 15         out yet?</p> <p>16          A. That's correct.</p> <p>17          Q. All right. Doctor, you say on page 22 of 18         your report that the TVTO device is accompanied by an 19         IFU and that you have reviewed the TVTO IFU. Correct?</p> <p>20          A. Please repeat that.</p> <p>21          Q. Yeah, I was reading that you have 22         reviewed the TVTO IFU and you find it adequate and 23         complete for its use in the operating room?</p> <p>24          A. Yes, I did.</p> <p>25          Q. And you said I understand that the IFU is</p>	<p>1           the known risks and adverse events in the IFU so that 2           information will be available to the doctor to pass on 3           to patient, do you agree with that?</p> <p>4           A. I expect Ethicon to state the risks 5           inherently associated to the mesh.</p> <p>6           Q. And do you agree with me that if Ethicon 7           fails to provide the necessary information regarding 8           the risks and adverse events and complications to the 9           doctor, there's a risk at that point that the patient 10          cannot be properly counseled because the information 11          has not been provided to the doctor, do you agree with 12          that statement?</p> <p>13          A. The IFU is intended to educate the 14          physician on the performance of the procedure. Part of 15          it is going to be the complications from the device 16          that remains on the patient.</p> <p>17          Q. Listen to my question. Do you agree with 18          me that if Ethicon fails to provide the necessary 19          information regarding the risks and adverse events and 20          complications to the doctor, there's a risk at that 21          point that the patient cannot be properly counseled?</p> <p>22          MS. GALLAGHER: Object to form.</p> <p>23          BY MR. FREESE:</p> <p>24          Q. Do you agree with that statement or not?</p> <p>25          A. We don't, we don't use the IFU for</p>
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<p>1           not a comprehensive guide for surgical treatment of 2           SUI. Do you see that?</p> <p>3           A. Yes, that's the way it's stated.</p> <p>4           Q. Do you agree that a doctor implanting a 5           TVTO should be allowed to rely solely upon the IFU to 6           ascertain what complications if any may result from the 7           use of that device in counseling his patient?</p> <p>8           A. I think that the IFU needs to speak about 9           the specifics of the implant, but the continence 10          procedure, the risk of the continence procedure 11          pertains to the formation and the training of the 12          doctor.</p> <p>13          Q. Well, that's not my question. My 14          question is, do you agree that a doctor should be able 15          to rely solely on the IFU and nothing else in educating 16          himself about the complications that could result from 17          the use of a device?</p> <p>18          A. No.</p> <p>19          Q. Is that reasonable or not?</p> <p>20          A. No, they should not rely just on the IFU.</p> <p>21          There's a wealth of data out there about the 22          indications and the use of the device.</p> <p>23          Q. Do you agree with me that in order for 24          Ethicon to do its best to make sure that a patient is 25          appropriately counseled, that Ethicon needs to provide</p>	<p>1           patient counseling.</p> <p>2           Q. Well --</p> <p>3           A. So I disagree, I disagree with the 4           statement that if it's not placed on the IFU, I expect 5           the IFU to address the complications that have to do 6           with the tape, it should give me direction on how to 7           use the device, but I, I don't expect them to give me 8           the benchmark for patient education.</p> <p>9           Q. And, Doctor, that question didn't involve 10          the IFU.</p> <p>11          A. Okay.</p> <p>12          Q. So, you have to listen to my question. 13          I'm just asking you if you agree with this statement, 14          that if Ethicon fails to provide the necessary 15          information regarding the risks and adverse events of 16          complications to a doctor, there's a risk at that point 17          that the patient cannot be properly counseled because 18          the information has not been provided to the doctor. 19          Do you agree with that?</p> <p>20          MS. GALLAGHER: Object to form.</p> <p>21          A. No, I disagrees with that because the 22          only source of information for a physician before they 23          counsel a patient is not Ethicon.</p> <p>24          BY MR. FREESE:</p> <p>25          Q. And do you agree or disagree that if</p>

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<p>1 Ethicon fails, if it happens that Ethicon fails to      2 provide material information about the risks of, for      3 example, a TVT or any medical device, to the physician,      4 if it actually happens and the doctor just relies on      5 the IFU regarding the risks and doesn't tell a patient      6 a risk that the doctor wasn't told about, the patient      7 would not have been properly counseled?</p> <p>8 MS. GALLAGHER: Object to form.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. Do you agree or disagree with that?</p> <p>11 A. I agree that if the doctor relies just on      12 the IFU, they will not be able to provide enough      13 counseling to the patient.</p> <p>14 Q. Do you know Dr. Hinoul?</p> <p>15 A. Yes.</p> <p>16 Q. He's a medical affairs director at      17 Ethicon, is he not?</p> <p>18 A. Yes.</p> <p>19 Q. He's a urogynecologist, is he not?</p> <p>20 A. He is.</p> <p>21 Q. He's trained the same way you're trained,      22 correct?</p> <p>23 A. I don't know if it was the same way, but      24 I know he's a urogynecologist.</p> <p>25 Q. And his job is to make sure that, from a</p>	<p>1 medical director for Ethicon.</p> <p>2 Q. Yes.</p> <p>3 A. So, so, the question is, is that the only      4 thing the doctor relies on, do I agree to that?</p> <p>5 Q. No, I'm asking do you agree with Dr.      6 Hinoul's answer, absolutely, to the question that was      7 just asked; do you agree with his answer?</p> <p>8 A. Yeah. In order for Ethicon to do its      9 best to make sure that a patient is properly counseled,      10 Ethicon needs to provide the known risks and events in      11 the IFU so that information will be available to a      12 doctor to pass on to the patient. Yes, that's --</p> <p>13 Q. You agree with that?</p> <p>14 A. If they're aware, if they're aware of any      15 complications, that will be, that's, Ethicon will have      16 to transmit it for the doctor to be aware.</p> <p>17 Q. If Ethicon is aware of a complication,      18 they have to transmit it to the doctor?</p> <p>19 MS. GALLAGHER: Object to form.</p> <p>20 A. I would agree that that's the only way      21 that the doctor could know.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. All right. Okay. And, he goes on to      24 say, "And, therefore, if Ethicon fails to provide the      25 necessary information regarding risks and adverse</p>
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<p>1 medical standpoint, that doctors are getting properly      2 warned of the risks of using TVT, correct?</p> <p>3 MS. GALLAGHER: Object to form.</p> <p>4 A. I'm not aware of his job description.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. When is the last time you talked to him?</p> <p>7 A. At an AUGS meeting.</p> <p>8 Q. Okay. You actually reviewed and logged      9 his deposition in this case, did you not?</p> <p>10 A. Yes, I did see one of his depositions.</p> <p>11 Q. I want to show you page 2007 and 2008 of      12 his deposition that was given January 14th, 2014, okay?      13 And you see where it says, quote, "In order for Ethicon      14 to do its best to make sure that a patient is      15 appropriately counseled, Ethicon needs to provide the      16 known risks and adverse events in the IFU so that      17 information will be available to the doctor to pass on      18 to the patient. Right?" And he says, "Absolutely."      19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Do you agree with his answer?</p> <p>22 A. If Ethicon is the only source, but I      23 think in the context in which he was asked, from what I      24 see from that answer, absolutely, is, is Ethicon going      25 to provide that information, and he's testifying as a</p>	<p>1 events and complications to the doctor, there's a risk      2 at that point that the patient cannot be properly      3 counseled because the information has not been provided      4 to the doctor, correct?" And Dr. Hinoul's answer is,      5 "That is correct." Do you see that?</p> <p>6 A. Yes, but I disagree with him because I      7 don't --</p> <p>8 Q. So, let me, first of all, did I read the      9 question and answer correctly?</p> <p>10 A. Yes, sir.</p> <p>11 Q. Do you agree with Dr. Hinoul?</p> <p>12 A. No, I don't agree that Ethicon is the      13 only source. In his answer, he's saying that, I mean,      14 there's this long, long question, and then he says he      15 agrees. The substance of it is Ethicon is not the only      16 source that I'm going to consider counseling my      17 patients.</p> <p>18 Q. It doesn't say only source. It says if      19 Ethicon fails to provide the necessary information      20 regarding risks and adverse events and complications.      21 to the doctor, there's a risk at that point that the      22 patient cannot be properly counseled because the      23 information has not been provided to the doctor,      24 correct? And Dr. Hinoul says that is correct, and you      25 disagree with that?</p>

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<p style="text-align: center;">Page 146</p> <p>1        A. Okay, the specific question there on what 2 can be inferred from the question, so I'm going to 3 answer to you the best, the best way I can answer is, 4 if Ethicon does not disclose it, if there's no 5 disclosure, there's no way for the physician to know it 6 unless it has to do with the procedure itself. Now, we 7 don't rely just on the IFU and we don't just rely on 8 Ethicon to tell us about the, the procedure.</p> <p>9        Q. I'm going to get there, Doctor. I just 10 want to know whether or not you agree or disagree with 11 what Dr. Hinoul just said there.</p> <p>12        MS. GALLAGHER: Objection to form. He's 13 explaining to you why he can't say agree or 14 disagree.</p> <p>15        MR. FREESE: Well, I'm not sure he is --</p> <p>16        MR. GOSS: I think the form is fine.</p> <p>17        MR. FREESE: Just form, that's all we 18 need.</p> <p>19        BY MR. FREESE:</p> <p>20        Q. Do you understand my question, Dr. 21 Sepulveda? I read you the question on lines 1 through 22 7 of page 1208 and the answer on line 8. All I want to 23 know is, do you agree with Dr. Hinoul or do you 24 disagree with Dr. Hinoul?</p> <p>25        MS. GALLAGHER: Objection to form.</p>	<p style="text-align: center;">Page 148</p> <p>1        A. I would disagree on that, no.</p> <p>2        Q. Even though Dr. Hinoul says absolutely, a 3 doctor should be able to rely solely on the IFU, you 4 disagree with Dr. Hinoul?</p> <p>5            MS. GALLAGHER: Object to form.</p> <p>6        BY MR. FREESE:</p> <p>7        Q. Correct?</p> <p>8        A. Yes, I don't think you're going to find 9 any physician that would agree with just relying solely 10 on the IFU.</p> <p>11        Q. Let me ask you this, Dr. Sepulveda. Who 12 knows more about the complications of Ethicon's 13 products, you or the medical affairs doctor at Ethicon?</p> <p>14        MS. GALLAGHER: Object to form.</p> <p>15        A. I think I'm in a privileged position to 16 know what kind of complications patients have when you 17 follow the IFU.</p> <p>18        BY MR. FREESE:</p> <p>19        Q. I'm asking you, who knows more about the 20 complications related to TVTs, Dr. Hinoul or you?</p> <p>21        MS. GALLAGHER: Object to form.</p> <p>22        A. I do.</p> <p>23        BY MR. FREESE:</p> <p>24        Q. Okay. So the jury should conclude that 25 Jaime Sepulveda knows more than the urogynecologist</p>
<p style="text-align: center;">Page 147</p> <p>1        A. I will have to disagree with that with 2 Dr. Hinoul, because it implies that the only source 3 that you have is Ethicon, and that's not the only 4 source that I have.</p> <p>5        BY MR. FREESE:</p> <p>6        Q. And you understand he was speaking on 7 behalf of Ethicon in his deposition?</p> <p>8        MS. GALLAGHER: Objection to form.</p> <p>9        A. Yes, he's the medical director for 10 Ethicon.</p> <p>11        BY MR. FREESE:</p> <p>12        Q. And the next question, "And, in fact, if 13 Ethicon fails, if it happens that Ethicon fails to 14 provide material information about the risks, for 15 example, of the TVT or any medical device, to the 16 physician, if that actually happens and the doctor just 17 relies on the IFU regarding the risks and doesn't tell 18 the patient the risks that the doctor wasn't told 19 about, the patient would not have been properly 20 counseled, correct?" His answer is, "I am in full 21 agreement, the surgeon should be able to rely solely on 22 the IFU, absolutely." Do you see that?</p> <p>23        A. For the patient counseling, solely on the 24 IFU?</p> <p>25        Q. Yes, sir.</p>	<p style="text-align: center;">Page 149</p> <p>1        hired by Ethicon to be its worldwide medical affairs 2 doctor, you know more than he does?</p> <p>3            MS. GALLAGHER: Object to form.</p> <p>4        A. Yes, I have implanted more TVTs than he 5 has.</p> <p>6        BY MR. FREESE:</p> <p>7        Q. Who has seen more internal documents 8 about the complications of the use of TVT, you or Dr. 9 Hinoul?</p> <p>10        A. Dr. Hinoul sees more internal documents.</p> <p>11        Q. It's not your job to write the IFUs for 12 TVT, is it, or TVTO?</p> <p>13        A. No, it's not, I don't write the IFUs.</p> <p>14        Q. You understand that all of the warnings 15 and complications that appear in a TVTO IFU are written 16 by the medical affairs people at Ethicon, correct?</p> <p>17        MS. GALLAGHER: Object to form.</p> <p>18        A. That's what I would expect to write it, 19 yes.</p> <p>20        BY MR. FREESE:</p> <p>21        Q. People like Dr. Hinoul?</p> <p>22        A. Yes.</p> <p>23        Q. He's the one in charge of making sure 24 it's accurate and full and gives the doctors all the 25 information they need regarding complications of the</p>

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<p>1 procedure, correct?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. He writes the IFU.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. And that's his job 24/7, correct?</p> <p>6 MS. GALLAGHER: Object to form.</p> <p>7 A. I don't know if it's 24/7. He writes the</p> <p>8 IFU.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. But that's his job, that's what a medical</p> <p>11 affairs director does, correct?</p> <p>12 A. I'm not familiar with their duties, but I</p> <p>13 think that he has an input on the IFU.</p> <p>14 Q. And yet, you would substitute your</p> <p>15 judgment for his on what a doctor should rely or not</p> <p>16 rely on out of the IFU?</p> <p>17 A. No, I did not testify on that. I said --</p> <p>18 Q. I'm asking you, is it your opinion</p> <p>19 that --</p> <p>20 MS. GALLAGHER: Don't cut him off,</p> <p>21 please.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. Sorry. Go ahead.</p> <p>24 A. What I testified is that I have placed</p> <p>25 more TVTOS, I've done more follow up on these patients</p>	<p>1 A. I can tell you that any of my 2,000</p> <p>2 patients have called him and say, Piet Hinoul, I'm</p> <p>3 doing great.</p> <p>4 Q. Let's do this, Doctor, can you we agree</p> <p>5 you don't know what, you have no personal knowledge of</p> <p>6 what Dr. Hinoul knows or he doesn't know?</p> <p>7 MS. GALLAGHER: Object to form.</p> <p>8 A. No, I already testified, I'm not aware of</p> <p>9 his job description.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. And you have no idea what he knows or</p> <p>12 what he doesn't know, do you?</p> <p>13 A. Actually, I --</p> <p>14 Q. My question is, what personal knowledge</p> <p>15 do you have of what Piet Hinoul knows or doesn't know</p> <p>16 about complications of TVT slings?</p> <p>17 A. I do not know. I just, I do not know</p> <p>18 that. I just --</p> <p>19 Q. And how many --</p> <p>20 MS. GALLAGHER: Please, let him finish</p> <p>21 his answer.</p> <p>22 MR. FREESE: Because he's now off, not</p> <p>23 responding to my question anymore. He's</p> <p>24 answered my question, now he editorializing.</p> <p>25 So, I mean, as long as I can charge the time</p>
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<p>1 than he has. I use the product, I would know about any</p> <p>2 problems it would have. I would not have continued to</p> <p>3 use the polypropylene mesh for midurethral slings to</p> <p>4 this day if I would have seen or I would have had any</p> <p>5 problems.</p> <p>6 MR. FREESE: Move to strike.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. That's not my question, sir. My question</p> <p>9 is simply, Doctor, you would substitute your judgment</p> <p>10 on what an implanting physician should rely on in the</p> <p>11 IFU over Dr. Hinoul's judgment about what a doctor</p> <p>12 should rely on or can rely on from the IFU, correct?</p> <p>13 MS. GALLAGHER: Object to form.</p> <p>14 A. No, Dr. Hinoul does the, he writes the</p> <p>15 IFU. Dr. Hinoul is in a, in a position to see skewed</p> <p>16 data of how the procedure performs, because I can tell</p> <p>17 you that Dr. Hinoul do not get a phone call or a report</p> <p>18 of how many patients have done better and how many</p> <p>19 patients have been improved in their quality of life.</p> <p>20 He gets --</p> <p>21 BY MR. FREESE:</p> <p>22 Q. How do you know that?</p> <p>23 A. He gets a report about complications.</p> <p>24 Q. How do you know that? How do you know</p> <p>25 what he gets?</p>	<p>1 back to you, I don't mind, but he can't sit</p> <p>2 here and read out of a telephone book, either.</p> <p>3 So, if it's not responsive to my question,</p> <p>4 we're wasting time. He's answered my question.</p> <p>5 If you want to ask him a question on redirect,</p> <p>6 that's fine.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. My question to you is you have no clue</p> <p>9 how many slings Dr. Hinoul has implanted, do you?</p> <p>10 A. Yeah, actually, I asked him.</p> <p>11 Q. And what was his answer?</p> <p>12 A. I, I, I probably remember that it was</p> <p>13 none here in the United States.</p> <p>14 Q. I didn't ask you that. How many slings</p> <p>15 has Dr. Hinoul implanted in his life?</p> <p>16 A. I think in my conversation with him at</p> <p>17 some point, I asked him if he could, if he could just</p> <p>18 come to clinical practice on this, on, on, on the</p> <p>19 United States, and he told me no, that he is a medical</p> <p>20 director.</p> <p>21 Q. Dr. Sepulveda, I have no idea what you</p> <p>22 just said. My question is just simply --</p> <p>23 A. I agree that I ramble. I agree with you</p> <p>24 on that.</p> <p>25 Q. Sir, I have a great deal of respect for</p>

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<p>1 you, let's try not to ramble. My question is simply,      2 do you know how many slings Dr. Hinoul has ever      3 implanted in his life?</p> <p>4 A. No, Mr. Freese, I don't know how many      5 slings he has implanted.</p> <p>6 Q. And do you know how many slings he has      7 taken out in his life?</p> <p>8 A. No.</p> <p>9 Q. Do you know how many peer-reviewed      10 articles he's written about slings?</p> <p>11 A. No, I'm only familiar with his articles      12 on the anatomy of TVTO.</p> <p>13 Q. You know he's written at length on TVT,      14 correct?</p> <p>15 A. He, for this case, I actually relied on      16 one specific article that he wrote about the anatomy.</p> <p>17 Q. My question is you understand that Dr.      18 Hinoul is published in peer-review articles, correct,      19 on TVTs?</p> <p>20 A. Yes.</p> <p>21 Q. You, sir, have published zero peer-review      22 articles on TVT slings, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And you've done 2 to 3,000 sling      25 procedures, correct?</p>	<p>1 information is based on my, on dissection of multiple      2 specimens, on the communications that I've had with my      3 peers, and on the, on the, on what's published,      4 although it is true that I have not published on TVT, I      5 am in the forefront of providing patient care, so I      6 know how this product performs.</p> <p>7 MR. FREESE: Move to strike,      8 non-responsive.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. Doctor, you have no personal knowledge of      11 how many doctors just like you that Dr. Hinoul talks to      12 every day in his job?</p> <p>13 A. I don't know who he talks to in his job.</p> <p>14 Q. He talks to you, right?</p> <p>15 A. No, we, we don't talk as part of his job.</p> <p>16 We, the last time we spoke we were sitting on a meeting      17 enjoying the presentations of the scientific meeting.</p> <p>18 Q. So, you were not talking about business      19 with Ethicon with Dr. Hinoul?</p> <p>20 A. No, I don't, I don't talk about those      21 things. We have, we have other subjects that we speak      22 about.</p> <p>23 Q. You understand Dr. Hinoul has access to      24 all the internal information available at Ethicon,      25 correct?</p>
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<p>1 A. Yes.</p> <p>2 Q. And you've only seen two or three      3 complications in your entire 2 to 3,000?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know how many complications Dr.      6 Hinoul has seen?</p> <p>7 A. In his line of work, probably has seen      8 more than three.</p> <p>9 Q. And, so, you've seen three out of 3,000,      10 you have no idea how many he's seen, yet you feel      11 comfortable saying you know more about complications      12 from slings and what doctors need to know than he does?</p> <p>13 A. No, I say I know more about outcomes. I      14 could say, I could say that I know more about outcomes.</p> <p>15 Q. You know about three complications out of      16 3,000, he may know way more than that. Yet you want to      17 say that your information is superior to his?</p> <p>18 MS. GALLAGHER: Object to form.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. I mean, you realize Dr. Hinoul is      21 responsible --</p> <p>22 A. I still have to answer your question.</p> <p>23 Q. I'm sorry. Go ahead.</p> <p>24 A. My, my information, my information is on      25 the, on the, on my clinical experience and my</p>	<p>1 A. Yes.</p> <p>2 Q. You do not, do you?</p> <p>3 A. I do not.</p> <p>4 Q. In fact, all you have available to you,      5 Dr. Sepulveda, is what the lawyers for Ethicon want to      6 show you, correct?</p> <p>7 MS. GALLAGHER: Object to form.</p> <p>8 A. In terms of the company documents, yes.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. Okay. So, the company documents, let's      11 define that, company documents about complications and      12 the frequency of complications, those type of documents      13 within Ethicon you don't have access to, do you?</p> <p>14 A. No, I do not have access to that.</p> <p>15 Q. Dr. Hinoul does, does he not?</p> <p>16 A. I think he does.</p> <p>17 Q. He has to. He's the medical affairs      18 director.</p> <p>19 A. He's the medical director for Ethicon.</p> <p>20 Q. Real quick, Dr. Sepulveda, you've never      21 measured the pore size of the TVT sling, have you?</p> <p>22 A. Yes.</p> <p>23 Q. Yes, you have never measured it?</p> <p>24 A. Yes, I have measured it.</p> <p>25 Q. Okay, when did you measure it?</p>

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<p>1        A. I put it together actually under the      2 microscope at the pathology at South Miami Hospital,      3 and I look at it and I measure it and then I confirmed      4 what it was. Not only that, the pore size, but also      5 the pore sizes with, with Prolift Plus M.</p> <p>6        Q. The Ultrapro?</p> <p>7        A. Prolift Plus M.</p> <p>8        Q. Ultrapro?</p> <p>9        A. It could be Ultrapro, but I did not take      10 it as Ultrapro.</p> <p>11       Q. Okay. What was the largest dimension of      12 the pore?</p> <p>13       A. On which one?</p> <p>14       Q. On Prolene.</p> <p>15       A. On the Prolene used for TVT was 1,200.</p> <p>16       Q. Okay. And what was -- but that's not      17 symmetrical, is it?</p> <p>18       A. No, because of the knit, because of the      19 way it's knitted, it could be 1,200, but it's never      20 less than a thousand on each side.</p> <p>21       Q. It's never less than a thousand and at      22 its greater point it's 1,200?</p> <p>23       A. Yes.</p> <p>24       Q. 1,200 microns?</p> <p>25       A. Microns.</p>	<p>1        Q. Let me stop you and do it one at a time,      2 okay? What is your basis for saying biomechanically      3 they will not operate the same?</p> <p>4        A. Well, they're two different types of      5 material.</p> <p>6        Q. Let me ask a better question. Have you      7 seen any internal documents from Ethicon saying that      8 they will act differently biomechanically?</p> <p>9        A. No, I have not seen any internal      10 documents. I have not read any internal documents.</p> <p>11       Q. If there are internal documents that say      12 they would behave similarly biomechanically, would you      13 have liked to have seen these documents?</p> <p>14       A. Either similarly or separate, but that's      15 just the first part of my answer.</p> <p>16       Q. I understand. We're taking them one at a      17 time. So you've seen no document that says it would,      18 that an Ultrapro TVTO sling would operate differently      19 than one made for a POP, correct?</p> <p>20       A. They're two different, those are two      21 different applications.</p> <p>22       Q. Okay, and you've never seen a single      23 internal document making that comparison, correct?</p> <p>24       A. No, I have not seen that comparison.</p> <p>25       Q. And whether or not Ethicon concluded</p>
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<p>1        Q. And what did you use to measure the      2 microns?</p> <p>3        A. There's a little caliber on the      4 microscope.</p> <p>5        Q. When did you do this?</p> <p>6        A. Years so.</p> <p>7        Q. Okay. It's not in your report anywhere.</p> <p>8        A. No.</p> <p>9        Q. Okay, why didn't you put it in the      10 report?</p> <p>11       A. I didn't think it was relevant because      12 the pore size have been well established by other      13 publications.</p> <p>14       Q. Did you record this somewhere when you      15 did it?</p> <p>16       A. No, I did not record that.</p> <p>17       Q. Why did you measure the pore size?</p> <p>18       A. Because I like to become familiarized      19 with what I implant in my patients.</p> <p>20       Q. What is the basis of your opinion that a      21 TVTO made out of Ultrapro is not a safer alternative      22 than a TVTO made out of Prolene?</p> <p>23       A. There's a few areas on that. Number one      24 is biomechanically, the TVT made of Ultrapro will not      25 behave in the same way that a TVT made of Prolene.</p>	<p>1        internally that it would be suitable to use Ultrapro in      2 a TVTO application?</p> <p>3        MS. GALLAGHER: Object to form.</p> <p>4        A. I have not seen, I have not that on      5 internal documents from Ethicon.</p> <p>6        BY MR. FREESE:</p> <p>7        Q. So your opinion is, I'm Dr. Sepulveda and      8 because they're two different applications my opinion      9 is they would behave differently?</p> <p>10       MS. GALLAGHER: Object to form.</p> <p>11       A. Yes, biomechanically, they would behave      12 differently. It's not that they would say that to me.</p> <p>13       BY MR. FREESE:</p> <p>14       Q. And it's so because Jaime Sepulveda says      15 it's so.</p> <p>16       A. No, that's not exactly the case. That      17 brings me to the --</p> <p>18       Q. Hold on, we'll stay on this for a second.      19 What is your basis other than it's my opinion that they      20 would behave differently biomechanically?</p> <p>21       A. By my biomechanical knowledge.</p> <p>22       Q. Okay. Have you conducted any      23 biomechanical testing of Prolene mesh versus Ultrapro      24 mesh?</p> <p>25       A. No, I have not conducted that test.</p>

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<p>1 Q. Okay. All right, what's your second 2 basis for saying that Ultrapro would not be suitable? 3 A. There was, the way they behave, in my, 4 when you're using it in the operating room, the way 5 they handle, they're different. 6 Q. I understand that's your opinion, but 7 you've done no bench testing on that, correct? 8 A. There's no bench testing on it. 9 Q. You've done no tensile testing, correct? 10 A. I have not done any of the bench testing 11 that would be required to make that conclusion. 12 Q. You've done no cadaveric testing on 13 Ultrapro as a sling versus Prolene, correct? 14 A. No, I have not done that test. 15 Q. And have you reviewed any of Ethicon's 16 internal cadaveric testing? 17 A. No. 18 Q. Do you know whether or not actually 19 Ethicon even tested Ultrapro in a sling application in 20 cadavers? 21 A. No, I'm not aware of their testing. 22 Q. So they didn't show you the results of 23 any cadaver testing for the use of Ultrapro as a sling 24 internally, correct? 25 A. I can not say, I can not under oath say</p>	<p>1 form objection? 2 MS. GALLAGHER: No, because you're asking 3 him about -- I thought the question had safety 4 in it and suitability. He's talking about 5 safer alternative design. That's a different 6 analysis. That's my objection. 7 MR. FREESE: Okay. 8 BY MR. FREESE: 9 Q. Let me clarify. You're answering, Dr. 10 Sepulveda, why Ultrapro would not be suitable or a 11 safer alternative than Prolene for use in a sling 12 application, correct? That's what you're answering? 13 A. In the sling application, yes. 14 Q. And you told me biomechanically, you 15 didn't think it would operate the same? 16 A. That's correct. 17 Q. All right, what's your next reason? 18 A. The second is that we already have a 19 device in place that has been tested extensively 20 clinically. So, whatever, whatever evidence is, comes 21 in has to be stronger than the evidence that we have on 22 TVT. 23 Q. All right. Now, the only, you say that 24 there's not demonstrating empirical evidence because 25 you haven't seen any, you don't know if it's been done</p>
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<p>1 that I'm aware of specific testing or, or experiment 2 that has been done. 3 Q. On anything, bench, cadaver, any kind of 4 application? 5 A. No, I'm not aware of that. 6 Q. All right, what was the next reason, 7 other than biomechanical, why you said that Ultrapro 8 would not be suitable as a sling? 9 MS. GALLAGHER: Object to form. 10 A. The next reason is that there have been 11 no clinical studies -- 12 MR. FREESE: Stop for a second. What's 13 the objection? I want to cure it. 14 MS. GALLAGHER: Because it's as a safer 15 alternative design, that's the question you're 16 asking him. 17 MR. FREESE: No, he told me that he had 18 three reasons why Ultrapro would not be 19 suitable as a, to be used as a TVTO. 20 MS. GALLAGHER: As a safer alternative 21 design is what you're questioning him about. 22 That's what he's answering. 23 MR. FREESE: Yes. 24 MS. GALLAGHER: Okay. 25 MR. FREESE: So, will you withdraw your</p>	<p>1 or not, you just haven't seen any, right? 2 A. Yes, there's, there has been no 3 presentations that I heard on conference, there has 4 been no texts that I have read, there has been no 5 scientific randomized control trials, not even a cohort 6 study that shows the use of a hybrid or partially 7 absorbable sling. 8 Q. So, basically, then, that would be just 9 the same as TVTO, wouldn't it? There were no 10 randomized control studies, there were no cohorts, any 11 of that done before TVTO was launched, correct? 12 A. No, that mischaracterizes my testimony on 13 the basis that they're different, they're two different 14 implants. The implant used on TVTO was the same 15 implant that was used on TVT. The implant that would 16 be used on Ultrapro is not the same as the implant that 17 would be used on TVTO. 18 Q. Well, it's the same implant that was used 19 in Prolift, was it not? 20 A. They are different applications. One 21 is -- 22 Q. They're both pelvic surgeries, are they 23 not? 24 A. Well, they're different applications. 25 One is urinary incontinence, the other one is prolapse.</p>

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<p>1       Q. Okay, so, you said that there was no      2 empirical science, and that is because you haven't seen      3 any, you don't know if there is empirical data within      4 Ethicon because you haven't seen that, but you're      5 simply saying you have not seen a published empirical      6 data comparing an Ultrapro as a sling versus a Prolene,      7 correct?</p> <p>8       MS. GALLAGHER: Object to form.</p> <p>9       A. There's no clinical evidence that shows      10 that using a partially-absorbable sling is superior to      11 the sling that we have used.</p> <p>12 BY MR. FREESE:</p> <p>13       Q. Okay, any other reason?</p> <p>14       A. Yeah, the third reason is the consensus      15 from the societies.</p> <p>16       Q. Well, what has the society said about      17 using Ultrapro as a sling?</p> <p>18       A. I trust that the societies will come up      19 with, with recommendations specifically on the use of      20 the established clinical standard for the treatment of      21 incontinence.</p> <p>22       Q. Should I interpret that to mean that the      23 relevant clinical societies have not commented one way      24 or the other about the use of Ultrapro as a sling?</p> <p>25       A. Actually, they have commented that</p>	<p>1       reason against it. It's silent.</p> <p>2       MS. GALLAGHER: Object to form.</p> <p>3       A. They have no evidence to speak one way or      4 the other.</p> <p>5       The fourth reason is that the FDA, the      6 panel on the FDA on the executive summary did not offer      7 that even as an alternative.</p> <p>8       MS. GALLAGHER: We have lunch. Do you      9 want to break?</p> <p>10       MR. FREESE: Sure.      11                     (A lunch break was taken from 1:17 p.m.      12 to 1:29 p.m.)</p> <p>13 BY MR. FREESE:</p> <p>14       Q. Dr. Sepulveda, I want you to turn to the      15 Roman numeral IV, expert opinion overview in your      16 report. I think it may be 55 on your version. It's      17 page 54 on mine, I think that's just because of the way      18 it's printed. Tell me when you get there.</p> <p>19       A. Yeah, I'm here.</p> <p>20       Q. Just so I understand, you give opinions      21 throughout your report, but is section IV intended to      22 sort of like summarize the important opinions that you      23 intend to give in a case?</p> <p>24       A. Yes.</p> <p>25       Q. Okay, I realize you give more than what's</p>
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<p>1       specifically the use of monofilament polypropylene is      2 the clinical standard on the case, on the treatment of      3 urinary stress incontinence.</p> <p>4       Q. I understand that. I'm asking -- my      5 question is different, that no society has said that,      6 that use of Ultrapro as a mesh sling would not be safer      7 than the current design?</p> <p>8       A. They have not recommended it, and they      9 have not said that it's safer.</p> <p>10       Q. So that's not really a reason because      11 they haven't said one way or the other, correct?</p> <p>12       A. As surgeons, we also follow the      13 recommendations of the societies.</p> <p>14       Q. I know, but the society has made no      15 assertion one way or the other, so there's nothing to      16 follow.</p> <p>17       A. I'm not saying the society, I'm saying      18 the societies, the clinical societies.</p> <p>19       Q. I understand, you're talking about AUGS      20 and ACOG and --</p> <p>21       A. Right.</p> <p>22       Q. And they have just not spoken to it,      23 correct?</p> <p>24       A. That's correct.</p> <p>25       Q. Okay, so that's not a reason for it or a</p>	<p>1       in section IV and we'll go back and visit about some of      2 that, but this expert opinion overview is sort of a      3 summary of the opinions that you're going to give?</p> <p>4       A. Yes.</p> <p>5       Q. Okay. All right. The fact that Jennifer      6 had UTIs, vaginal infections before the implantation of      7 the TVTO, is the significance of that is that you're      8 saying there's not a cause and effect with the mesh      9 because she was suffering from these incidents earlier?</p> <p>10       A. Right, that's, these are two very      11 frequent conditions in women.</p> <p>12       Q. And, so, the fact that she had urinary      13 tract infections before she had mesh is your opinion      14 that the mesh didn't cause any UTIs?</p> <p>15       A. That's correct.</p> <p>16       Q. Okay. Mesh can cause UTIs, can it not?</p> <p>17       A. If you have a mesh that actually      18 obstructs the urethra, it can cause urinary tract      19 infections.</p> <p>20       Q. And you said that she had reported      21 dyspareunia before the implantation of the mesh,      22 correct?</p> <p>23       A. Yes.</p> <p>24       Q. Do you know how long before that and how      25 many times in her life she ever reported dyspareunia?</p>

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<p>1           A. I know of at least one instance in which 2       she reported. 3           Q. And I do, too, that's all I can find. 4       So, can we agree that you and I can only find one 5       reported incident of dyspareunia prior to the 6       implantation of the mesh? 7           A. Yeah, we can agree on that. 8           Q. And that fact is the basis for your 9       opinion that the mesh didn't cause dyspareunia because 10      she reported it at one time previous in her life? 11          MS. GALLAGHER: Object to form. 12          A. And, again, there's, that's not the only 13       reason why I say that she may have dyspareunia, and 14       there are other conditions within the surgery itself, 15       within her clinical course itself that could predispose 16       to dyspareunia. 17          BY MR. FREESE: 18          Q. And we'll talk about those, but having it 19       before the implant one time is part of your opinion why 20       it's not being caused by the mesh now? 21          A. That's part of it. 22          Q. Okay. You said that she had two previous 23       devices implanted, an IUD and an Essure. 24          A. Yes. 25          Q. And had complications with the IUD which</p>	<p>1       Jennifer alleges in this lawsuit are not in any way 2       impacted or caused by the Essure, in your opinion? 3           A. I don't see a relationship between the 4       Essure and any claims that I have read. 5           Q. Okay. So, we can take Essure off the 6       table as being relevant to anything that's going on 7       with Jennifer today? 8           A. On her symptoms that she's complaining of 9       now, yes. 10          Q. And that would be true of her IUD also? 11          A. That's correct. 12          Q. Okay. Was her only risk factor for SUI 13       three vaginal deliveries? 14          A. That's the largest risk factor actually, 15       yes. 16          Q. And that's the only one that you 17       identified in your report, is that correct? 18          A. Well, there's no way to know by family 19       history based on the medical records, which is also a 20       very, very strong risk factor, and three vaginal 21       deliveries and an early age delivery. 22          Q. Okay, so, three deliveries, early age, 23       and possibly family but you don't know? 24          A. Exactly. 25          Q. You're not going to give an opinion about</p>
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<p>1       led to its removal. 2          A. Yes. 3          Q. Okay, what's the significance of that? 4          A. Any time that you may have any implant, 5       there is a risk to have it removed. 6          Q. Okay. So, you're saying the fact that 7       she had an IUD that got a complication and had to be 8       removed, why is that relevant to your opinion in this 9       case? 10          A. There's an understanding from, from Mrs. 11       Ramirez that whenever anything can be implanted, it may 12       need to be removed. 13          Q. The Essure, what is the relevance of that 14       in your opinions? 15          A. Well, Essure is an implant that is 16       permanent. 17          Q. Okay. 18          A. It either stays there or it absorbs, and, 19       again, I'm in a much better position to give testimony 20       about a sling, but in general, what I know about Essure 21       is just about what I read about the product. I have 22       to, I want to be accurate and say that I have not 23       implanted Essure, but it's just another implant. 24          Q. Okay, and just so I won't waste any time 25       on it, the injuries and problems and harms that</p>	<p>1       what all doctors know, are you? 2          A. I don't understand the question. 3          Q. Well, I mean, you say that, that doctors 4       from their med school, residency, fellowship, that 5       risks of incontinence pelvic surgery are all well known 6       to doctors. You're not here to give an opinion what 7       all doctors know, are you? 8          A. No, I can not testify what all doctors 9       know, but I can do, say what's required from us in the, 10       in the guidance to get us credentialed and be board 11       certified. 12          Q. You know what you were taught in medical 13       school, correct? 14          A. Yes. 15          Q. And you know what you were taught in your 16       residency? 17          A. Yes. 18          Q. You don't know what everyone else was 19       taught in medical school or their residency? 20          A. I don't know what they were taught. I 21       know about the requirements to pass the examinations. 22          Q. And you don't intend on offering any 23       opinions about what doctors know about pelvic surgery 24       or complications from pelvic surgery? 25          A. I can offer an opinion about the, what</p>

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<p>1 we, the complications that are for each surgery.      2 Q. Based on your personal experience?      3 A. And also on, on what has been reported.      4 Q. All right. You note in here that you      5 trained Dr. Reyes.      6 A. He came, he came to, to see me to do      7 surgery.      8 Q. Do you know Dr. Reyes?      9 A. I can, I cannot recall when he came to      10 see me.      11 Q. Okay, and the reason I'm asking, if I      12 brought three people into the room, could you tell me      13 which one was Dr. Reyes?      14 A. No.      15 Q. Okay. Did you go back, or did somebody      16 supply you with a roster of attendees and you learned      17 that he attended one of your courses?      18 A. No, I did not see a roster, but if he      19 testified that, I believe he testified that he came to      20 see me.      21 Q. You're relying on what Dr. Reyes said,      22 not your memory?      23 A. Not my memory, no.      24 Q. Okay, you don't remember the guy, nobody      25 has told you in the record that he's ever been in any</p>	<p>1 to look first through the IFU, and from beginning to      2 completion, I want you all to be familiar with this,      3 because at the end of this, you're going to have this      4 document going with you, going with you home, when      5 you're home.      6 Q. And am I correct that you are instructed      7 by Ethicon to, to teach from the IFU, that is supposed      8 to be your guide?      9 A. I do not remember having those specific      10 instructions that you have to teach by the IFU, but if      11 I'm opening the device, I'm going to use the IFU.      12 Q. Because it's there, right?      13 A. The IFU is right there.      14 Q. And you understood that you were not      15 supposed to teach anything that was inconsistent with      16 the IFU, correct?      17 A. I have no reason to teach anything that      18 was different.      19 Q. I understand, but you understood that      20 Ethicon told you, because of regulatory reasons, you      21 can't, you can't represent or teach anything that is      22 inconsistent with our, with our copy-approved IFU?      23 A. I could not represent anything different      24 from what the IFU said.      25 Q. And you didn't, did you?</p>
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<p>1 of your classes, you're simply relying on what his      2 testimony was?      3 A. That's correct.      4 Q. Do you recall what the class was that you      5 taught?      6 A. No, I don't recall the specific one.      7 Q. You said I've trained pelvic surgeons      8 including Dr. Reyes. You don't know that, you're      9 just --      10 A. I know by what has been said, okay, he      11 came to see you.      12 Q. Okay. All right. You say, quote, "The      13 IFU was taught during these training sessions as well      14 as a surgeon-to-surgeon discussion of technique,      15 placement, risks and treating complications." Do you      16 see that?      17 A. Yes.      18 Q. You don't know what you taught him, so      19 you don't know what was taught?      20 A. If he came to see me in a cadaver lab, I      21 had a system for every time I would go, we would go      22 into the specimen, and that system consisted of opening      23 the IFU, and every time that I had the three or four      24 doctors dissecting the cadaver with me, the program was      25 always the same, we're going to insert it, we're going</p>	<p>1 A. I did not.      2 Q. So up until --when is the last time you      3 did any TVT training, sir?      4 A. Long time ago, I would say over six      5 years, at least over six years.      6 Q. Okay, so, 2010?      7 A. Yes.      8 Q. Okay. And, so, as of the last time you      9 taught the, any TVT training, you would have been using      10 the, the applicable IFU, correct?      11 A. Yes, for any, any device, I always      12 started with the IFU.      13 Q. And you realize that the, that the      14 warnings in the TVTO IFU haven't changed in any      15 material way since 2004 to 2015?      16 MS. GALLAGHER: Object to form.      17 A. I, I, I've heard, I overheard, this is      18 just hearsay, that they have changed. I haven't looked      19 at an IFU, even though I place, specifically this last      20 Monday, you know, Monday or, yeah, this week, I have      21 not, did not look at the IFU.      22 BY MR. REESE:      23 Q. When is the last time you looked at the      24 IFU to TVTO?      25 A. Probably the last course that we went</p>

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1      through. 2      Q. About six years ago? 3      A. About six years ago. 4      Q. And whatever was in that TVT IFU in 2010 5      is what you taught physicians about the risks, 6      complications, adverse effects of the use of the 7      product, correct? 8            A. That was what we used for, to explain to 9      the physicians. 10        Q. Okay. You said, Doctor, that there was a 11     much higher risk of major injury from the hysterectomy 12     to which Jennifer consented, especially as to 13     complaints of pelvic pain and dyspareunia. Do you see 14     that? 15        A. Yes. 16        Q. What complications do you believe were 17     caused by her hysterectomy, if any? 18        A. There is a higher risk of dyspareunia 19     from a hysterectomy than from a sling. 20        Q. Well, I hear that, but that's not my 21     question. What if any complications do you believe 22     Jennifer is suffering from today that was caused by the 23     hysterectomy? 24        A. The pain on deep penetration on the left 25     side.	1      down and contribute to the bowstring sensation that Dr. 2      Graham felt. 3            Q. Okay. We'll talk about that also in a 4      second. So, the dyspareunia, pelvic pain and 5      bowstringing of the mesh were caused by the 6      hysterectomy? 7            A. The hysterectomy contributed to it. 8            Q. Okay. Did any other doctor conclude that 9      a complication of the hysterectomy caused any of those 10     problems, other than you? 11        A. Repeat that. 12        Q. Yes, sir. I understand Dr. Sepulveda 13     says the hysterectomy caused the dyspareunia, it caused 14     the groin pain, it contributed to the bowstringing of 15     the mesh. Correct? 16        A. Yes. 17        Q. Did any other doctor who actually treated 18     her reach that conclusion? 19        A. No. 20        Q. Okay. And Dr. Reyes laid hands on her, 21     correct? 22        A. Yes. 23        Q. He didn't reach that same conclusion, did 24     he? 25        A. No.
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1      Q. Okay. And why is that? 2      A. Because, although this was a laparoscopic 3      hysterectomy, the closure was the same closure that is 4      used in a vaginal hysterectomy, and patients that have 5      a vaginal hysterectomy have a risk of having 6      dyspareunia and pelvic pain, especially if, as it was 7      in her case, not properly healed. 8      Q. And so you believe her dyspareunia is 9      caused by a complication from a hysterectomy? 10     A. Yes. 11     Q. Do you believe that her groin pain is 12     caused by a complication of the hysterectomy? 13     A. The groin pain is likely caused by the 14     hysterectomy, and the procedure itself, the sling, the 15     sling can produce groin pain, but there's a closer 16     proximity from the vaginal cuff to the groin than from 17     the sling. 18     Q. Okay. Vaginal pain, groin pain. Any 19     other complaint that Jennifer has that you think was 20     caused by the hysterectomy, or complications from 21     hysterectomy? 22     A. Yes, basically the pain and the, and the 23     dyspareunia, and I also believe that the hysterectomy, 24     the uterus being central to the support on the upper 25     third of the vagina also produced the vagina to come	1      Q. Dr. Graham laid hands on her, did he not? 2      A. That's correct. 3      Q. He did not reach that conclusion, did he? 4      A. He did not. 5      Q. Dr. Zimmern laid hands on her, didn't 6      reach that conclusion, did he? 7      A. No. 8      Q. Dr. Chen saw Jennifer, did she not? 9      A. Yes. 10     Q. She did not reach that conclusion, did 11     she? 12     A. No. 13     Q. You are the only doctor that says the 14     hysterectomy is causing any of her complications? 15     A. I'm the only physician to my knowledge 16     that has mentioned that. 17     Q. Doctor, I want to make sure that you and 18     I are saying the same thing. I'm saying do you have an 19     opinion whether or not the hysterectomy caused any or 20     all of these problems, and you're answering it 21     contributed to it. So, I want to make sure we're on 22     the same page. When you say contribute, do you mean 23     cause? 24     A. Well, she had two surgeries. She had the 25     hysterectomy, and then she has the, the, she had the

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<p>1 sling and she had the hysterectomy. In addition to 2 that, then she had the revision surgery. 3 Q. Surgeries? 4 A. She has more than, yes, so there are two, 5 she had the, the sling, the hysterectomy, the revision 6 by Dr. Graham and the revision by Dr. Zimmern. 7 Q. Yes, sir. When I asked you did the 8 hysterectomy, or complication from the hysterectomy 9 cause the dyspareunia, cause the pelvic pain, cause the 10 bowstringing, and you said it contributed to it, you're 11 saying it contributed to causing all those things? 12 A. It contributed to, I see that as an 13 explanation for the symptoms that she has. I know that 14 dyspareunia, that there was a pain during sex that was 15 referred on the left side before she saw Dr. Graham. 16 Once she had that, that revision, dyspareunia cleared 17 and she did not refer to dyspareunia for over a year. 18 So, the hysterectomy contributed to the lack of support 19 in the area, that was obviously a relaxation in the 20 compartment of the pelvis, and what was placed when the 21 upper part came down, that's what you felt. 22 Q. Did the mesh contribute in any way to any 23 of the injuries or, or harm that Jennifer is claiming 24 in this lawsuit? 25 A. There's more evidence pointing out to all</p>	<p>1 A. I think that's, what's included in the 2 IFU is not pain just because of the mesh. It's pain of 3 any surgery that would include an implant, so -- 4 Q. Including mesh, though? 5 A. Including mesh. That's explained in the 6 IFU. Why did they decide to put pain in that specific 7 area? I don't know. I can tell -- what I do know is 8 that mesh by itself, just leaving polypropylene in that 9 area will not cause pain. 10 Q. Even though the IFU says that it can? 11 A. Even if the IFU says that, I can tell to 12 my patient, I can look at my patients in the eye and 13 tell them mesh by itself do not cause pain. 14 Q. I understand. Even though the IFU for 15 the mesh written by Ethicon says it can cause pain? 16 A. That's correct, even when they say it can 17 cause pain. 18 Q. And it says it can cause dyspareunia, 19 correct? 20 A. It says it can cause dyspareunia, yes. 21 Q. And it says it can cause nerve damage? 22 A. Yes. 23 Q. Okay. You just disagree that it can do 24 any of those things, even though Ethicon admits that it 25 can?</p>
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<p>1 the other etiologies or causes that we already saw, 2 than to the mesh by itself causing pain. 3 Q. That's not my question. I'm asking you, 4 did the mesh in any manner, in any percentage, 5 contribute to causing any of Jennifer's injuries? 6 A. No, I don't believe that's -- 7 Q. So you're saying not only was it, you're 8 saying there's other things that were more likely, 9 you're saying definitively, it played zero percent in 10 causing her dyspareunia, zero percent in causing any 11 groin or vaginal pain, zero percent in causing any 12 bowstringing, any of the bowstringing of the mesh 13 itself? 14 A. I think when you rule in and you rule out 15 things, you cannot go by a zero percent or one percent. 16 You can say that on the context of a randomized control 17 trial, but when you look at the different causes, rule 18 it in and rule it out, I can rule out mesh as the 19 immediate cause of her pain based on the evidence that 20 mesh by itself does not cause pain. 21 Q. Well, what is -- mesh does not cause 22 pain? 23 A. No. 24 Q. Okay. Why is it in, why is it in the IFU 25 then? That's a complication of the use of mesh.</p>	<p>1 A. It's there in the IFU, and it has been 2 described without validation. I can, from a biological 3 point of view, there's no evidence that leaving a piece 4 of mesh on tissue causes pain by itself. 5 Q. So, in your view, Doctor, is mesh capable 6 of causing any injury to a woman, of any kind? 7 A. I think that when you place it in the, in 8 the safe area that it's used for, for slings, it should 9 not cause an injury. 10 Q. So it's your testimony that a sling, if 11 properly placed, is impossible of causing any injury to 12 anyone? 13 MS. GALLAGHER: Objection, form. 14 A. By itself, a sling, any surgery for 15 incontinence obviously can produce pain. Any surgery 16 for incontinence can produce dyspareunia. It's just 17 that to do the surgery with mesh doesn't contribute 18 over what we know already about continence procedures. 19 BY MR. FREESE: 20 Q. So, in your opinion, the hundred thousand 21 lawsuits that are pending in this country against 22 Ethicon and AMS and Bard and Boston Scientific, every 23 one of them are frivolous, correct? 24 MS. GALLAGHER: Object to form. 25 A. No, I did not say that.</p>

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<p style="text-align: center;">Page 186</p> <p>1 BY MR. FREESE:      2 Q. Let's talk about it. You believe every      3 one of those cases are frivolous because mesh can't      4 possibly cause any of these injuries?      5 MS. GALLAGHER: Object to form.      6 A. I don't think that I will have enough      7 hours in my day to look at each one of them. I can      8 only give an opinion of the ones that I have reviewed.      9 BY MR. FREESE:      10 Q. And of the ones you've reviewed, a      11 hundred percent of the time you've said the mesh didn't      12 cause any harm to the woman, correct?      13 A. The pain caused directly by the mesh, I      14 can say that mesh by itself does not cause pain.      15 Q. One hundred percent of the time on cases      16 you've reviewed for Ethicon, you've said the mesh      17 caused no harm to the woman, correct?      18 A. That's correct.      19 Q. You will agree that the FDA believes that      20 the mesh is capable of causing pain in and of itself,      21 do you not?      22 A. By itself, an implant of mesh or      23 polypropylene?      24 Q. Yes.      25 A. They, they say that there were reports of</p>	<p style="text-align: center;">Page 188</p> <p>1 BY MR. FREESE:      2 Q. Well, you've relied on the Dear Health      3 Care Professional letter that was sent out by the FDA,      4 were you not? The public health notification?      5 A. Yes, I do remember that.      6 Q. In fact, you were saying Dr. Reyes was      7 aware of it, too, correct?      8 A. Yes, with any surgery, mesh or no mesh,      9 there's a risk of pain and there's a risk of      10 dyspareunia.      11 Q. But you don't believe that there really      12 is, even though the FDA says that?      13 A. No, what I just say is that mesh by      14 itself is just the whole surgery. What I say is that      15 mesh by itself, just implanting a piece of mesh, just      16 leaving a piece of polypropylene suture on my tissue      17 does not cause pain.      18 Q. Well, there's more than just laying it.      19 You have to surgically implant it, correct?      20 A. Well, there is a pubovaginal sling      21 procedure done.      22 Q. So, the process of implanting mesh is      23 capable of causing pain and causing injury, is it not?      24 A. Yes, the actual use, or the actual      25 procedure can cause pain.</p>
<p style="text-align: center;">Page 187</p> <p>1 it, we have gone over the MAUDE database, and there are      2 reports, even in trials, of mesh causing pain, the      3 procedure using mesh causing pain. It's just that when      4 we look at the different procedures, for example, we      5 look at the trial for colposuspension, the rate of pain      6 is higher.      7 Q. That's not my question, Dr. Sepulveda.      8 You understand that the FDA says that synthetic      9 midurethral slings can cause dyspareunia, can cause      10 pain?      11 A. Yes, that's in the warning.      12 Q. And the FDA is saying, in addition to the      13 warning, the FDA says it, correct?      14 A. Yes, they said it, that's the only way      15 that they have communicated about this, to my      16 knowledge, through the warning.      17 Q. And you just don't believe it?      18 A. I believe that mesh by itself does not      19 cause pain.      20 Q. You don't believe the FDA when they say      21 mesh complications are caused by the mesh?      22 MS. GALLAGHER: Object to form.      23 A. No, I, I cannot believe or misbelieve it      24 because I'm not aware of them saying exactly mesh is      25 what causes the pain.</p>	<p style="text-align: center;">Page 189</p> <p>1 Q. And it's your opinion that in this case,      2 neither the procedure nor the mesh contributed in any      3 way to Jennifer's injuries?      4 A. Yeah, I think that there are things that      5 can be ruled in to the better extent than the mesh.      6 Q. I understand that and we'll talk about      7 that, but I'm asking you about the mesh. You have      8 ruled it out as a contributor in any way to her      9 injuries, correct?      10 A. Yes, mesh sitting in there by itself,      11 polypropylene sutures just sitting there by itself do      12 not cause pain.      13 Q. We're not talking about polypropylene      14 sutures. We're talking about a Prolene mesh, not      15 sutures. You're saying the TVTO sling did not cause or      16 contribute to Jennifer's injuries in any way?      17 A. Yeah, I don't think, it is my opinion      18 that the TVTO was not the cause of dyspareunia and      19 pain.      20 Q. Or any nerve damage?      21 A. No, no nerve damage.      22 Q. Now, you say the mesh contributed in no      23 way to her dyspareunia, pain, nerve damage. Multiple      24 treating doctors disagree with you, the ones who are      25 not paid to testify do believe that her complications</p>

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<p style="text-align: center;">Page 190</p> <p>1    were caused by the mesh, correct?</p> <p>2            MS. GALLAGHER: Object to form.</p> <p>3            A. There are doctors that just look at the 4       mesh as a cause of pain. Case in point, Dr. Graham 5       felt before his surgery, based on his testimony and on 6       the operative report, that the mesh was causing 7       bleeding, that the mesh, the implant, the midurethral 8       sling was causing bleeding and was causing pain, but he 9       discovered during the surgery that the actual source of 10      bleeding was the scars on the vaginal vault.</p> <p>11      BY MR. FREESE:</p> <p>12      Q. So Dr. Graham thought it was the mesh 13       going into surgery, but after surgery, he concluded 14       that it was the hysterectomy granulation that was 15       causing the problem?</p> <p>16      A. Yes, he actually, he actually took the 17       vaginal vault tissue and he took the, the piece of mesh 18       that he felt was a bowstring with the belief that she 19       was going to g 20       et better, and obviously she continued with it. She 21       continued with the symptoms.</p> <p>22      Q. Dr. Sepulveda, I'm going to mark this as 23       Exhibit 16 to your deposition.</p> <p>24      (Plaintiff's Exhibit No. 16 was marked 25       for identification.)</p>	<p style="text-align: center;">Page 192</p> <p>1            A. Pelvic pain from transobturator tape and 2       vaginal bleeding.</p> <p>3            Q. Well, how can that be? I thought you 4       said he got in there and discovered that it was the 5       hysterectomy causing the pain and not the mesh?</p> <p>6            A. Well, before his -- when you look at his 7       records from the preop visit --</p> <p>8            Q. All right, let's look at this record. Do 9       you agree with me that his operative report, preop says 10      that the transobturator tape is causing Jennifer's 11      pain?</p> <p>12      A. Yes.</p> <p>13      Q. He goes in there, he partially removes 14      the left side of the sling, correct?</p> <p>15      A. Yes.</p> <p>16      Q. Comes out and dictates contemporaneously 17      with his surgery his findings, correct?</p> <p>18      A. Yes.</p> <p>19      Q. And his postoperative diagnosis is 20      identical to his preoperative diagnosis?</p> <p>21      A. He dictated that.</p> <p>22      Q. So you would agree with me that your 23      conclusion about what he found is not borne out by Dr. 24      Graham's medical records. He said both before surgery 25      and after surgery it was the tape that was causing</p>
<p style="text-align: center;">Page 191</p> <p>1      BY MR. FREESE:</p> <p>2      Q. These are Dr. Graham's records. Okay?</p> <p>3      And let's see if his records agree with what you say.</p> <p>4      I'll just hand you my copy and we'll work on it</p> <p>5      together. I think it's easier. You see that this is</p> <p>6      the operative report of Dr. Graham?</p> <p>7      A. Yes.</p> <p>8      Q. And it's dated December 22nd, 2010?</p> <p>9      A. Yes.</p> <p>10     Q. All right. And you say Dr. Graham</p> <p>11     thought it was the mesh that was causing her pain</p> <p>12     before surgery, but he got in, did the partial revision</p> <p>13     and came out thinking the hysterectomy was causing the</p> <p>14     pain?</p> <p>15     A. Yes.</p> <p>16     Q. Okay. Let's see what his operative</p> <p>17     report says. Preoperative diagnosis: Pelvic pain from</p> <p>18     transobturator tape, vaginal bleeding. Do you see</p> <p>19     that?</p> <p>20     A. Yes.</p> <p>21     Q. That's before he goes in and does the</p> <p>22     surgery, correct?</p> <p>23     A. Yes.</p> <p>24     Q. Tell the jury what his postoperative</p> <p>25     diagnosis is.</p>	<p style="text-align: center;">Page 193</p> <p>1      Jennifer's injury, correct?</p> <p>2      A. He used the same diagnosis.</p> <p>3      Q. Okay. He found that the pelvic pain was</p> <p>4      caused by the transobdurator tape.</p> <p>5      A. He just used the same diagnosis.</p> <p>6      Q. All right. Well, he's saying that the</p> <p>7      reason that I thought the tape was causing pain after</p> <p>8      surgery was in fact the very same reason he thought</p> <p>9      before surgery, correct?</p> <p>10     A. Yeah, but I just, I just say he used the</p> <p>11     same diagnosis, and we use diagnoses like that every</p> <p>12     time we dictate to say the diagnosis is the same.</p> <p>13     Q. I understand, but that's inconsistent</p> <p>14     with your testimony, isn't it?</p> <p>15     A. No, it's not.</p> <p>16     Q. You're saying Dr. Graham went in and</p> <p>17     preoperatively said it was the tape and postoperatively</p> <p>18     said it was the hysterectomy that was causing her pain.</p> <p>19     A. No, he cannot say that the hysterectomy</p> <p>20     caused it, because the hysterectomy happened remotely</p> <p>21     to it.</p> <p>22     Q. Well, but you're saying it. She had the</p> <p>23     hysterectomy six years ago, but you have no hesitation</p> <p>24     six years later saying that the hysterectomy is causing</p> <p>25     her pain, not the tape, right?</p>

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<p>1        A. He wouldn't know --</p> <p>2        Q. Correct? You're saying six years after</p> <p>3        the fact that the hysterectomy caused the pain.</p> <p>4        Correct?</p> <p>5        A. Yes.</p> <p>6        Q. You weren't there for the hysterectomy,</p> <p>7        correct?</p> <p>8        A. No.</p> <p>9        Q. Okay, and you're saying Dr. Graham</p> <p>10      wouldn't know because he wasn't there for the</p> <p>11      hysterectomy, correct?</p> <p>12      A. No.</p> <p>13      Q. But he did the revision surgery, did he</p> <p>14      not?</p> <p>15      A. Yes, he did.</p> <p>16      Q. And he concluded it was the tape that was</p> <p>17      causing the pain, not the hysterectomy, correct?</p> <p>18      MS. GALLAGHER: Object to form.</p> <p>19      A. No, he revised, he revised the vaginal</p> <p>20      vault.</p> <p>21      BY MR. FREESE:</p> <p>22      Q. Sir, I'm not arguing that he revised the</p> <p>23      vaginal vault. He dictated that postoperatively the</p> <p>24      pain was caused by the TVTO tape, correct?</p> <p>25      A. Yes.</p>	<p>1        Q. Okay. And he says that on palpation I</p> <p>2        was able to feel the left side of her transobturator</p> <p>3        mesh at its insertion into the obturator muscle. Do</p> <p>4        you see that?</p> <p>5        A. Yes.</p> <p>6        Q. Is that an expected outcome? Do you</p> <p>7        expect the doctor to be able to palpate the mesh after</p> <p>8        it's been implanted for six months or a year?</p> <p>9        MS. GALLAGHER: Object to the form.</p> <p>10      A. Under normal circumstances, you don't</p> <p>11      feel the tape. There are instances in which you can</p> <p>12      feel the tape if you palpate hard enough.</p> <p>13      BY MR. FREESE:</p> <p>14      Q. But if this was what you would expect,</p> <p>15      Dr. Graham wouldn't have been able to feel that tape;</p> <p>16      that's an unwanted result if you can palpate the tape,</p> <p>17      correct?</p> <p>18      A. No, you can actually feel the tape and</p> <p>19      you can feel the tape when there's hyper-relaxation of</p> <p>20      the side wall.</p> <p>21      Q. Okay, well, he doesn't say that. He says</p> <p>22      he was able to palpate. He's not talking about</p> <p>23      relaxation. Let me just ask you this way, then. Is</p> <p>24      Dr. Graham reporting that the fact that him palpating</p> <p>25      the tape is a normal finding or abnormal finding?</p>
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<p>1        Q. That is inconsistent with your testimony,</p> <p>2        is it not?</p> <p>3        A. No, that's -- yeah, that is inconsistent</p> <p>4        with my testimony, that is correct.</p> <p>5        Q. And you would agree with me nowhere in</p> <p>6        his postoperative report does Dr. Graham mention the</p> <p>7        hysterectomy as causing or contributing in any way to</p> <p>8        Jennifer's pain?</p> <p>9        A. No, it's the substance of the report</p> <p>10      shows that he revised the vaginal vault. There was no</p> <p>11      way there was going to be a scar in the vaginal vault</p> <p>12      if she would not have had a hysterectomy.</p> <p>13      MR. FREESE: Move to strike.</p> <p>14      BY MR. FREESE:</p> <p>15      Q. Dr. Sepulveda, you're not listening to my</p> <p>16      question. He, in his postoperative diagnosis, nowhere</p> <p>17      suggests that the hysterectomy played any role in</p> <p>18      causing Jennifer's pain, correct?</p> <p>19      A. He does not say that in his postoperative</p> <p>20      diagnosis.</p> <p>21      Q. And that is inconsistent with your</p> <p>22      testimony, is it not?</p> <p>23      MS. GALLAGHER: Object to form.</p> <p>24      A. That is inconsistent with my testimony.</p> <p>25      BY MR. FREESE:</p>	<p>1        A. No, that's a finding that you can, you</p> <p>2        can feel or you can describe in, in other slings. On</p> <p>3        this specific case, the reason why, why he takes Mrs.</p> <p>4        Ramirez to the operating room is because he feels that</p> <p>5        this is what's causing the pain.</p> <p>6        Q. I understand that, he's felt before the</p> <p>7        surgery and after the surgery it was causing her pain,</p> <p>8        correct?</p> <p>9        A. Yeah, he has the impression that's what's</p> <p>10      causing the pain, that that area that he palpated, that</p> <p>11      area of the bowstringing is what is causing the pain.</p> <p>12      He documents that, and after he does his surgery, he is</p> <p>13      certain that, because he put it on his postdiagnosis,</p> <p>14      that that's what caused the pain.</p> <p>15      Q. Okay. And you just think he's just flat</p> <p>16      out wrong?</p> <p>17      A. I think that I would not characterize it as</p> <p>18      flat out wrong.</p> <p>19      Q. I'm sorry, you think he's wrong?</p> <p>20      MS. GALLAGHER: Form.</p> <p>21      A. I think that the assessment of this sling</p> <p>22      causing the pain in the presence of scar tissue is</p> <p>23      general and is not accurate.</p> <p>24      BY MR. FREESE:</p> <p>25      Q. Okay, he's wrong. I mean, that's,</p>

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<p>1 inaccurate is a nice way of saying he's wrong.      2       A. No, inaccurate is inaccurate, wrong      3 wrong. Wrong would have been if he goes in there and      4 says this is the cause of any other, any other symptom.      5 No, he feels that that's what's causing the pain, and      6 he had the advantage of examining Jennifer ahead of      7 time.      8       Q. He did, and he had the advantage of      9 examining her ahead of time and after he did the      10 surgery, and his conclusion after he had that advantage      11 of before and after was that the tape was causing her      12 pain, correct?      13       MS. GALLAGHER: Object to form.      14       A. That's his assessment.      15 BY MR. FREESE:      16       Q. Now, real quick on this bowstringing.      17 Are you saying that is a finding, a normal finding of      18 how the tape should feel, in a bowstring?      19       A. No, every time you place a sling you can      20 feel that, but there are other things that contribute      21 to you feeling it.      22       Q. And we're going to talk about that. I'm      23 simply asking you, is the finding of the mesh being      24 palpable and bowstringing, is that a normal finding in      25 your view?</p>	<p>1       A. It's as necessary as the excision of the      2 vaginal vault.      3       Q. And you have no criticism of Dr. Graham      4 for doing that surgery?      5       A. I do not have any criticism of Dr. Graham      6 for performing that surgery.      7       Q. And taking 1.5 centimeters of that TVTO      8 sling was both in his judgment correct and in your      9 judgment the correct and necessary thing to do      10 medically?      11       A. I don't think that he could have offered      12 much more beyond, if he felt, if he felt that, you      13 cannot offer much more.      14       Q. And am I correct, Dr. Sepulveda, we will      15 find nowhere in Dr. Graham's medical records where he      16 imputes or finds that the hysterectomy in any way      17 caused or contributed to Jennifer's injuries, can we      18 agree to that?      19       A. There's no, no description of it, but      20 afterwards, he documents that he had to, he had to take      21 a piece of scar tissue from the vaginal vault.      22       Q. I understand, but he nowhere says that      23 was the cause of her pain, does he?      24       A. No, he does not place that as a cause of      25 her pain.</p>
<p style="text-align: center;">Page 199</p> <p>1       A. No, palpating the sling and feeling pain      2 when you palpate the sling is not a normal finding.      3       Q. And that's what Dr. Graham found, isn't      4 it?      5       A. He did not word it like that, but he      6 obviously, from his diagnosis, that's what he felt.      7       Q. And you just think he's not right?      8       MS. GALLAGHER: Object to form.      9       A. I just, I just gave testimony on what      10 he --      11 BY MR. FREESE:      12       Q. I'll withdraw the question. He did, he      13 was able to induce pain on the left side along the      14 mesh, was he not?      15       A. I don't see a reason why anyone would      16 take someone to the operating room if there's no pain      17 on that side.      18       Q. Was Dr. Graham's surgery medically      19 necessary?      20       A. I think that at the time that he did it,      21 was what he felt was an appropriate way to, to handle      22 it.      23       Q. Can you answer my question now? Was Dr.      24 Graham's revision surgery and taking 1.5 centimeters of      25 mesh out of Jennifer a medically necessary procedure?</p>	<p style="text-align: center;">Page 201</p> <p>1       Q. Only you did that.      2       MS. GALLAGHER: Object to form.      3       A. Yes.      4 BY MR. FREESE:      5       Q. Doctor, you performed a differential      6 diagnosis on Jennifer?      7       A. As much as I can, I performed a, through      8 the, through all this, all these documents, I, I did      9 perform a differential diagnosis when she, I actually      10 performed a diagnosis when I examined her. But, yes,      11 I, as I see the whole, the whole extent of the whole      12 content of the medical records, I, I'm considering      13 things that I can rule in or I can rule out.      14       Q. Yes, sir. So, my question is, when you      15 were forming your opinions, were you attempting to rule      16 out or rule in mesh as a cause of Jennifer's pain when      17 forming your causation opinion?      18       A. I considered all the factors. I      19 considered the surgery, the mesh, the hysterectomy, and      20 I looked at what are the, what are the risks that has      21 been described with these surgeries for each one of      22 those conditions.      23       Q. So you're saying you both attempted to      24 rule it out and rule it in?      25       A. Yes, I actually look at what's more</p>

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<p>1 frequent, what's statistically more frequent, what is 2 more likely, what is less likely. 3 Q. Can you tell me every reason that you 4 rely on to give the opinion that you ruled the mesh out 5 as a cause of her pain?</p> <p>6 A. When you're, when you're doing your 7 differential diagnosis, there is a hierarchy of things 8 that are more frequent and less frequent. When you're 9 ruling in and ruling out different conditions, you have 10 a hierarchy of, of things that you can, you rule in and 11 you rule out, and part of it is how frequent each 12 complication is, and part of it is what were the 13 different components to, to the surgery.</p> <p>14 Q. Okay. And, so, just so I understand, I'm 15 trying to move us along here, so I understand it, are 16 you saying you ruled out the mesh because statistically 17 speaking, complications like Jennifer is complaining 18 about statistically happen more in hysterectomy 19 surgeries than mesh surgeries?</p> <p>20 A. There's a higher risk of dyspareunia and 21 pelvic pain associated to hysterectomy, especially to 22 vaginal hysterectomy, than to midurethral synthetic 23 sling.</p> <p>24 Q. Okay. Which this was not a vaginal 25 hysterectomy.</p>	<p>1 Q. Okay. So, based on what you know, Dr. 2 Sepulveda, Dr. Reyes implanted the TVTO in precisely 3 the way Ethicon told him to? 4 MS. GALLAGHER: Objection to form. 5 A. He implanted the, I would agree that he 6 implanted the TVTO in a way that is explained on the 7 instructions for use. 8 BY MR. FREESE: 9 Q. Then he did it the way Ethicon told him 10 to? 11 A. Well, I don't want to say that Ethicon 12 will tell him how to do it. I will have to say that he 13 used what's included on the procedure, and he also used 14 his knowledge of how to do a sling. 15 Q. We're talking past each other. I'm 16 simply trying to get you to agree with me that, based 17 on your review of all the records and the deposition 18 testimony, Dr. Reyes implanted the TVTO in the manner 19 described as proper in the eye of you? 20 A. I would agree with that. 21 Q. Okay, thank you. And you don't ascribe 22 any blame for any of Jennifer's problems to the device 23 or the manner in which Dr. Reyes implanted the device 24 in Jennifer? 25 A. I agree with that, too.</p>
<p style="text-align: center;">Page 203</p> <p>1 A. Actually, the only thing that was not 2 vaginal was the, the taking of the ligaments on the 3 upper part of the uterus, because on her vaginal 4 closure, Dr. Reyes specified that he closed the vagina 5 from the vaginal approach.</p> <p>6 Q. Was the hysterectomy medically necessary?</p> <p>7 A. In Dr. Reyes' judgment, which I would 8 defer to him, it was necessary.</p> <p>9 Q. Do you have any criticism at all about 10 Dr. Reyes?</p> <p>11 A. No, I don't have a criticism of how he 12 actually chose the procedures for Jennifer.</p> <p>13 Q. So you have no criticism of him choosing 14 the TVTO, correct?</p> <p>15 A. No, I think he did that on his best 16 judgment.</p> <p>17 Q. Based on everything you can tell, Dr. 18 Reyes implanted the TVTO in precisely the way that 19 Ethicon's instructions for use instructed him to do it, 20 correct?</p> <p>21 A. I have no way to actually say that that's 22 the way he did it, I wasn't, I was not there obviously, 23 but what I can get from the records, he describes a 24 procedure that is in accordance to most procedures that 25 I have read.</p>	<p style="text-align: center;">Page 205</p> <p>1 Q. Doctor, on page, my page 57, it's the 2 paragraph that starts once placed a mesh. Do you see 3 that?</p> <p>4 A. Yes, I do remember that. But I'll find 5 it. Yes.</p> <p>6 Q. So, if you'll drop down about halfway, 7 there's a sentence that says, quote, "A torn levator 8 muscle, a thin pubococcygeus muscle or relaxed ATFP 9 will provide very little support to a sling."</p> <p>10 A. Yes.</p> <p>11 Q. Now, I want to talk about that. Why is 12 that significant to your opinion?</p> <p>13 A. It's something that we found on the 14 cadaver dissections. If we would use a cadaver and we 15 would detach the different areas of support, the sling 16 fell down with the, with the areas of support. In 17 other words, the, the sling holds on the same line that 18 the periurethral support holds. If you detach any of 19 the components of the periurethral support, you will 20 tent the sling down.</p> <p>21 Q. Okay. And do you have an opinion that 22 Jennifer suffered a torn levator muscle?</p> <p>23 A. Levator muscle injuries are frequent.</p> <p>24 Q. Okay, that's not my question. I didn't 25 ask you how frequent it is. Do you have an opinion</p>

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<p>1      whether or not Jennifer had a torn levator muscle?</p> <p>2      A. Yes.</p> <p>3      Q. Okay, and your opinion is she did have a</p> <p>4      torn levator muscle?</p> <p>5      A. Yes.</p> <p>6      Q. That's the same thing as a levator</p> <p>7      avulsion, correct?</p> <p>8      A. Yes.</p> <p>9      Q. That's the phrase you used in your report</p> <p>10     is that she had a levator avulsion.</p> <p>11     A. That is correct, that's the phrase I</p> <p>12     used.</p> <p>13     Q. And that's a separation of the</p> <p>14     musculo-tissue from the pubic bone?</p> <p>15     A. That is a separation of the, of the</p> <p>16     levator, which is composed by different muscles, from</p> <p>17     the pubic bone.</p> <p>18     Q. When did she suffer this levator</p> <p>19     avulsion?</p> <p>20     A. At the time of her deliveries.</p> <p>21     Q. Well, at the time of her first delivery?</p> <p>22     A. That's when most of the injuries are</p> <p>23     sustained.</p> <p>24     Q. You didn't see any records after her</p> <p>25     first delivery reporting a levator avulsion, correct?</p>	<p>1      Q. Dr. Carey did not find a levator</p> <p>2      avulsion, did she?</p> <p>3      A. No.</p> <p>4      Q. Dr. Scott did not find a levator</p> <p>5      avulsion, did she?</p> <p>6      A. No, she found the features of a levator</p> <p>7      avulsion.</p> <p>8      Q. Doctor, did she diagnose levator</p> <p>9      avulsion?</p> <p>10     A. No.</p> <p>11     Q. Did Dr. Margolis find a levator avulsion?</p> <p>12     A. No.</p> <p>13     Q. There are at least seven to ten doctors</p> <p>14     who have worked or performed medical procedures on</p> <p>15     Jennifer, from her, from her childbirths through her</p> <p>16     pelvic surgeries. Right?</p> <p>17     A. Yes.</p> <p>18     Q. None of them found that she had a levator</p> <p>19     avulsion except you, correct?</p> <p>20     A. None of them diagnosed it.</p> <p>21     Q. You were the only one to find this</p> <p>22     avulsion, correct?</p> <p>23     A. That's correct.</p> <p>24     Q. And you think that this avulsion that no</p> <p>25     other doctor could find and no other doctor diagnosed</p>
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<p>1      A. No.</p> <p>2      Q. Okay, she had a second delivery. Do you</p> <p>3      think that's when this avulsion occurred?</p> <p>4      A. I would say that it most likely happened</p> <p>5      in the first one. Second and third one contributed to</p> <p>6      it.</p> <p>7      Q. Can we agree, Dr. Sepulveda, that of her</p> <p>8      three vaginal deliveries, not a single treating</p> <p>9      physician ever diagnosed her with a levator avulsion?</p> <p>10     A. I agree with you on that.</p> <p>11     Q. Okay. And can we agree that Dr. Reyes,</p> <p>12     who did pelvic surgery on her, did not find a levator</p> <p>13     avulsion?</p> <p>14     A. I agree with that.</p> <p>15     Q. Dr. Graham did not find a levator</p> <p>16     avulsion, correct?</p> <p>17     A. No.</p> <p>18     Q. Dr. Zimmern did not find a levator</p> <p>19     avulsion, correct?</p> <p>20     A. He may have encountered a levator</p> <p>21     avulsion or defined an upper levator avulsion.</p> <p>22     Q. He doesn't say that anywhere, does he?</p> <p>23     A. No, he does not.</p> <p>24     Q. Dr. Chen does not find that, does she?</p> <p>25     A. No.</p>	<p>1      was the cause of the bowstringing of her tape?</p> <p>2      A. I believe it has been there all along.</p> <p>3      Q. That was my point. You believe this</p> <p>4      levator avulsion existed before she ever saw Dr. Reyes</p> <p>5      for the implant to start with?</p> <p>6      A. Yes.</p> <p>7      Q. And what is the basis of that opinion?</p> <p>8      A. It's the, the papers on levator avulsion.</p> <p>9      Q. That was a poor question. Let me ask a</p> <p>10     better question. What in Jennifer's medical records</p> <p>11     lead you to believe that she had this levator avulsion?</p> <p>12     A. Well, she had a, first she had three</p> <p>13     vaginal deliveries. Second, there was hypermobility of</p> <p>14     the urethra.</p> <p>15     Q. When was hypermobility of her urethra</p> <p>16     first reported?</p> <p>17     A. On Dr. Reyes' examination.</p> <p>18     Q. Okay.</p> <p>19     A. Then, the hysterectomy was a</p> <p>20     precipitating factor on making the avulsion evident.</p> <p>21     Q. The hysterectomy took an existing levator</p> <p>22     avulsion and aggravated it?</p> <p>23     A. Yes.</p> <p>24     Q. All right.</p> <p>25     A. The levator avulsion manifested then on</p>

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<p style="text-align: center;">Page 210</p> <p>1 the feeling of the bowstringing on the side. It 2 continued to cause pain during activity. 3 Q. What pain and during what activity? 4 A. The pain that she testified that she was 5 having when she would just go on an activity, when she 6 would stretch. 7 Q. Okay, the pain that she reported 8 post-implant, correct? 9 A. That's correct. 10 Q. She didn't report any of these, that pain 11 pre-implant, correct, this activity pain? 12 A. No, there was a report of dyspareunia and 13 pelvic pain before, but you cannot relate that to a 14 levator avulsion. 15 Q. This fact of pain during activity that 16 Jennifer reported, exercise and stretching and all 17 that -- 18 A. Yes. 19 Q. -- that was after the mesh, correct? 20 A. After she had the surgeries. 21 Q. Okay. Never reported that prior to the 22 mesh implant? 23 A. No. 24 Q. Okay. Go on, I didn't mean to stop you. 25 A. And then the, the pain, the pain after</p>	<p style="text-align: center;">Page 212</p> <p>1 Q. But she didn't diagnose that, did she? 2 A. No. 3 Q. Let me ask you this, Dr. Sepulveda. 4 You're not licensed to practice medicine in Texas, are 5 you? 6 A. No. 7 Q. Never have been? 8 A. No, never have been. 9 Q. You know all of Jennifer's treating 10 doctors are all doctors licensed to practice medicine 11 in the state of Texas? 12 A. Yes. 13 Q. Okay. How did all these Texas licensed 14 doctors miss, over all these years, what you were able 15 to find in a few-minute IME? 16 MS. GALLAGHER: Object to form. 17 A. I did not find it in a few-minutes IME. 18 I actually looked at the whole continuum of care. Why, 19 why was I able to find it, what is the difference in 20 terms of certifications or qualifications between me 21 and all the other doctors that are in this case? 22 There's one exam, and it is the Pelvic Rehabilitation 23 Practitioner certification. 24 Q. Is this that Wallace thing? 25 A. Yes, this is the Herman &amp; Wallace</p>
<p style="text-align: center;">Page 211</p> <p>1 the, after the implant where the ischiorectal fossa was 2 approached -- I'm sorry, I'm going to rephrase that. 3 The pain after the explant surgery, where the 4 ischiorectal fossa was approached. 5 Q. Okay. Which explant surgery, Zimmern's 6 or Graham's? 7 A. The one that she had with Dr. Zimmern. 8 Q. Okay. I'm sorry, I'm not understanding 9 which pain you're talking about. The pain -- can you 10 say it again? 11 A. The pain after the explant surgery 12 performed by Dr. Zimmern where the ischioanal fossa fat 13 was exposed. 14 Q. Go ahead. 15 A. The contraction of the right levator, 16 described by Dr. Kelly Scott, with the low tone 17 described by 1 out of 5 on the left side, and my exam 18 in which I placed a Q-tip on the vagina and saw the 19 orientation of the vagina dropping from the left side 20 and keeping the right side up. 21 Q. That was during your IME? 22 A. Yes. 23 Q. Okay. So, Dr. Scott made some findings 24 that you think demonstrate this levator injury, right? 25 A. Yes.</p>	<p style="text-align: center;">Page 213</p> <p>1 certification, yes. 2 Q. Okay, so that Wallace certification is 3 what makes you more qualified to make this diagnosis 4 than all these double board-certified physicians? 5 A. I am -- 6 MS. GALLAGHER: Form. 7 A. -- double board-certified, too. 8 BY MR. FREESE: 9 Q. I understand, but the only thing that 10 makes you different, sir, is that you have this, this 11 certificate from this, this little organization in 12 Seattle that trains physical therapists, right? 13 A. Right. 14 MS. GALLAGHER: Object to form. 15 BY MR. FREESE: 16 Q. What's the full name, Wallace what? 17 A. It's Herman &amp; Wallace Institute for 18 Pelvic Floor Rehab. 19 Q. Okay, and the fact that you hold that 20 certification from them gives you the qualification to 21 make this levator avulsion diagnosis that every, every 22 doctor that treated Jennifer seemed incapable of 23 finding, correct? 24 MS. GALLAGHER: Object to form. 25 A. In addition to my double certification in</p>

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<p style="text-align: center;">Page 214</p> <p>1    pelvic floor rehab, yes.      2    BY MR. FREESE:      3       Q. We've got other doctors that have that,      4       don't we? Zimmern's got that, Dr. Margolis has got      5       that.      6       A. Yes.      7       Q. Okay. But they don't have the Wallace      8       physical therapy certificate?      9       A. If that's the way you want to refer to      10      it, it's your deposition.      11      Q. What did you do? It was like, like a      12      hundred multiple questions or something? What did you      13      do for that certificate, sir?      14      A. It's a five-hour exam.      15      Q. Okay, and just, like a multiple choice      16      test?      17      A. Yes.      18      Q. Okay.      19      A. With clinical scenarios.      20      Q. Anything other than a multiple choice      21      test?      22      A. No, it's clinical scenarios and it's a      23      secure examination.      24      Q. Okay. Who has been published in more      25      peer-reviewed journals regarding complications arising</p>	<p style="text-align: center;">Page 216</p> <p>1       Q. You have not peer reviewed a single      2       article of his, have you?      3       A. No, I have not.      4       Q. But his articles are peer reviewed, are      5       they not?      6       A. I just don't know if there's any      7       publication that I'm aware of that I have not seen,      8       that I have, I may have missed on the course of this      9       litigation about a peer-review article from Dr.      10      Philippe Zimmern or any other doctors that you      11      mentioned, on mesh.      12      Q. Okay. And if those exist, would you      13      modify your opinion?      14      A. If those would exist, I would welcome      15      reviewing it and modify my opinion accordingly.      16      Q. Okay. Well, how would you modify your      17      opinion? I mean, would you agree with Dr. Zimmern's      18      conclusions and say, you know what, he's got a      19      peer-reviewed publication, I don't, I would probably      20      defer to him on his conclusions on what is causing      21      Jennifer's problems?      22      MS. GALLAGHER: Object to form.      23      A. I think that most of the doctors are      24      taking care of patients.      25      BY MR. FREESE:</p>
<p style="text-align: center;">Page 215</p> <p>1    out of surgery from pelvic mesh, Dr. Zimmern or you?      2       A. No, he has had more publications on mesh.      3       That's one thing that he concentrates on.      4       Q. And to be a peer-reviewed author like he      5       is, that means all the experts in the field, that is      6       the doctors who do this for a living, like what you do,      7       they look at his work and say, okay, this is either      8       good science or this is crappy science, right? That's      9       what they do, peer review, right? They look at it and      10      say this is good, reliable science or it's not,      11      correct?      12      A. Can, can you show me a peer-review      13      article from Dr. Zimmern on mesh?      14      Q. Sure.      15      A. One peer-review article? Peer review,      16      I'm not talking about editorials, I'm talking about      17      peer review, randomized control trial on mesh, can you      18      show me one?      19      Q. A randomized control trial? No, I don't      20      know if I can or not.      21      A. I would welcome to read that any time you      22      provide me with that.      23      Q. You have not peer reviewed a single thing      24      that he has published, have you?      25      A. What's your question?</p>	<p style="text-align: center;">Page 217</p> <p>1       Q. Answer my question, Dr. Sepulveda. If I      2       showed you a peer-reviewed article from Dr. Zimmern on      3       pelvic mesh complications, will you then defer to his      4       conclusions on what was caused Jennifer's problems?      5       MS. GALLAGHER: Object to form.      6       A. If I find a peer-review article that      7       supercedes any of the available evidence that we have      8       now of randomized control trials or cohort studies in a      9       good sample, I will be willing to modify my opinion.      10      BY MR. FREESE:      11      Q. And we know you've never been peer      12      reviewed in any kind of publication regarding pelvic      13      mesh, correct?      14      A. No. I just take exams.      15      MS. GALLAGHER: Are you moving to      16      something else?      17      MR. FREESE: I can. You want to take a      18      break?      19      MS. GALLAGHER: No, because he hasn't      20      finished the levator stuff. He's talked about      21      what he saw in the records, but he hasn't      22      talked to you about images yet, so I don't      23      think you're done.      24      MR. FREESE: You want to just give me his      25      testimony there?</p>

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<p>1           MS. GALLAGHER: Well, I want you to get      2       all of his opinions. You started making fun of      3       his certifications before you got all of his      4       reasons for the levator.      5           THE WITNESS: Can we take a five-minute      6       break?      7           MR. FREESE: Of course.      8           (A break was taken from 2:27 p.m. to 2:33      9       p.m.)      10          BY MR. FREESE:      11          Q. We're going to get back to levators, but      12       real quick before I forget, the Wallace Institute, am I      13       correct, sir, that you don't even list it on your CV as      14       one of your qualifications?      15          A. It may have been missed from it. I may      16       have had it --      17          Q. Well, here's your CV that you attached to      18       your report here.      19           (Plaintiff's Exhibit 17 was marked for      20       identification.)      21          BY MR. FREESE:      22          Q. How long have you held this certification      23       from the Wallace Institute?      24          A. I think it's about two years.      25          Q. Two years, okay, and you realize this is</p>	<p>1       telling me the evidence of why you think that Jennifer      2       suffered a levator avulsion and you told me. Then Ms.      3       Gallagher suggested you talk to me about images, so let      4       me ask you about images. What do the images show in      5       relation to your opinion about a levator avulsion?      6           A. There are two images. One is the      7       ultrasound of the pelvic floor, and the other one is      8       the MRI.      9           Q. Okay, and I'm going to hand you Exhibit 6      10       from Dr. Zimmern's deposition. I'm going to hand you a      11       bunch of exhibits from Dr. Zimmern's deposition. Are      12       the images that you're referring to in here, and can      13       you pull them out and show me what you're talking      14       about?      15          A. Yes. There's the MRI, and there is the      16       ultrasound.      17          Q. Okay. Pull out everything, every image      18       that you think supports the levator avulsion and we'll      19       mark it.      20          MS. GALLAGHER: That you're putting in      21       front of him?      22          MR. FREESE: Yeah, I'm not trying to      23       trick him, this is what I've got. If you have      24       something else, Doctor, please volunteer.      25          MS. GALLAGHER: I think we've got all of</p>
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<p>1       the CV that you produced this week to us, Exhibit 17?      2          A. Yes.      3          Q. And that Wallace Institute certification      4       doesn't appear on your CV, does it?      5          A. No, I actually missed to place it in.      6          Q. Okay. Is it anywhere on any CV that you      7       prepared?      8          A. No, I'll update it, I'll update it, I'll      9       send you an updated copy.      10       Q. So, do I not have the most updated      11       version of your CV?      12       A. I thought it was, until now that you      13       pointed out that I haven't included that certification.      14       Q. Am I correct that 90 percent or more of      15       the members of that institute aren't even medical      16       doctors?      17       A. No, they're therapists, they're doctors      18       in physical therapy and rehabilitation.      19       MR. FREESE: Move to strike.      20       BY MR. FREESE:      21       Q. Dr. Sepulveda, am I correct that more      22       than 90 percent of the people who hold that Wallace      23       certification are not medical doctors?      24       A. That is correct.      25       Q. All right. Before our break you were</p>	<p>1       the actual films.      2          MR. FREESE: Okay.      3          MS. GALLAGHER: Because they're on the      4       CDs. They're not in hard copy.      5       BY MR. FREESE:      6          Q. Well, does what I put in front of you      7       adequately allow to you express the opinion about      8       evidence of a levator avulsion, or do you need      9       something else?      10       A. No, this is, this is, I think, I see two      11       images here that would help me with it.      12       Q. Okay. I don't want to withhold anything      13       from you that's going to help --      14       A. But there are two more images on the MRI.      15       These MRI images are exactly the same, the same image.      16       Q. We don't need the duplicates, then.      17       A. These are the only one. And there are      18       multiple images on the ultrasound actually.      19       Q. Okay.      20       A. Sorry, I correct, there are multiple      21       images on the MRI.      22       MR. FREESE: Let's mark this as Exhibit 18, and      23       this as Exhibit 19.      24       (Plaintiff's Exhibits No. 18 and No. 19      25       were marked for identification.)</p>

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<p style="text-align: center;">Page 222</p> <p>1 BY MR. FREESE:</p> <p>2 Q. First of all, tell us what Exhibit 18 is.</p> <p>3 A. Exhibit 18 is a picture of a, four images</p> <p>4 that are used for a pelvic floor ultrasound.</p> <p>5 Q. Okay. And you believe that that, these</p> <p>6 images help demonstrate the levator avulsion that you</p> <p>7 concluded that Jennifer has?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Can you, I'm going to give you</p> <p>10 different choices here of colors, you have a pen, can</p> <p>11 you point to me where in the image is evidence of the</p> <p>12 levator avulsion?</p> <p>13 A. You'll see in here.</p> <p>14 Q. Exhibit 18, right?</p> <p>15 A. We're on Exhibit 18, and the image that</p> <p>16 I'm going to, I'm going to write as A, I'm going to go</p> <p>17 to the one that is B, the other one is C, and the other</p> <p>18 one D.</p> <p>19 Q. Okay.</p> <p>20 A. So, I'm going to, these are mid sizeable</p> <p>21 images.</p> <p>22 Q. If you would, let's do it out here in the</p> <p>23 white so when we copy it we'll know. Would you put A,</p> <p>24 B, C and D on the white so we can -- or is the</p> <p>25 placement itself important?</p>	<p style="text-align: center;">Page 224</p> <p>1 up better.</p> <p>2 A. This is, I'm going to delineate the</p> <p>3 normal shape of the vagina, which is in the form of a</p> <p>4 butterfly, here, and this place is collapsed.</p> <p>5 Q. So just put an arrow there, put collapsed</p> <p>6 vagina. Okay. Now, can I see the avulsion, or is that</p> <p>7 just evidence of the avulsion?</p> <p>8 A. That's what supports, the levator is what</p> <p>9 supports the vaginal wall, and in this specific case,</p> <p>10 now we're looking at it, this is an image that should</p> <p>11 be looked at this way, because the vagina has this</p> <p>12 shape, and you see no tape here on the left side, and</p> <p>13 there's tape going to the right side. Same thing here.</p> <p>14 These are not separate images, this image is a</p> <p>15 construction of these three images. So you have this,</p> <p>16 this butterfly with a collapsed vagina here, tape here,</p> <p>17 no tape on the left side. The urethra is not</p> <p>18 collapsed. There is no indication of the tape on the</p> <p>19 urethra, and there's normal tissue between the urethra</p> <p>20 and the tape.</p> <p>21 Q. Can we see the avulsion on any of these</p> <p>22 images?</p> <p>23 A. Not on the ultrasound.</p> <p>24 Q. Okay. So, how does a medical doctor</p> <p>25 diagnose an avulsion?</p>
<p style="text-align: center;">Page 223</p> <p>1 A. No, no, this is just to, to say that</p> <p>2 this, this is the image I'm going to refer to.</p> <p>3 Q. So put it here in the white so we can see</p> <p>4 it clear.</p> <p>5 A. Okay.</p> <p>6 Q. Now, where on Exhibit 18 does it show</p> <p>7 this levator avulsion?</p> <p>8 A. There's, this is midsize images, A and B</p> <p>9 on this side, both images, and C is a coronal image,</p> <p>10 and this constructs a 3D rendering of the pelvic floor.</p> <p>11 Here you see the pubis, here you see the urethra, here</p> <p>12 you see the tape, clearly there's the tape.</p> <p>13 Q. You're on D, and let's go ahead, if you</p> <p>14 will, let's just pick a color that picks up on this.</p> <p>15 A. A line here, and I put tape.</p> <p>16 Q. Sure, that's good. Put tape.</p> <p>17 A. This is a tape, and this is the vagina,</p> <p>18 and the vagina is in the form of a butterfly. The</p> <p>19 vagina is in a form of a butterfly, but on this side,</p> <p>20 it's just collapsed. It's collapsed on the left side.</p> <p>21 The vagina just fell down, which is what I had</p> <p>22 described before.</p> <p>23 Q. Okay. So would you pick one of those</p> <p>24 markers and circle where you say the vagina has fallen</p> <p>25 down. Use the colors that Jordan brought, it will pick</p>	<p style="text-align: center;">Page 225</p> <p>1 A. You suspect it clinically by the</p> <p>2 deviation of the symmetry of the vagina, and with</p> <p>3 pelvic floor ultrasound you look at it.</p> <p>4 Q. You use an ultrasound to diagnose the</p> <p>5 levator, do you not?</p> <p>6 A. Yes, it's a clinical, a clinical based on</p> <p>7 subjective data based on what you find in your exam and</p> <p>8 you confirm it with a pelvic floor ultrasound.</p> <p>9 Q. Okay. And this is a pelvic floor</p> <p>10 ultrasound, correct?</p> <p>11 A. This is the pelvic floor ultrasound.</p> <p>12 Q. Where is the levator avulsion in here?</p> <p>13 A. You see the manifestation of the levator</p> <p>14 avulsion on the collapsed vagina on this side.</p> <p>15 Q. Let me make sure I understand. What</p> <p>16 you're saying is the manifestation is simply the result</p> <p>17 of the levator avulsion, correct?</p> <p>18 A. Right. If you see, if you're looking at</p> <p>19 the --</p> <p>20 Q. Did I say that correct?</p> <p>21 A. You did say that correct.</p> <p>22 Q. That's all I'm asking. Are you saying</p> <p>23 that an ultrasound cannot actually see the levator</p> <p>24 avulsion itself?</p> <p>25 A. Yes, it can, but in this view of the</p>

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<p>1 ultrasound, you cannot see the levators.</p> <p>2 Q. So, in Exhibit 18, we're looking at a</p> <p>3 pelvic ultrasound, it does not show us a levator</p> <p>4 avulsion, correct?</p> <p>5 A. It does not show the levator muscle. I</p> <p>6 cannot conclude, based on this image, that there's a</p> <p>7 levator, except for the vagina being collapsed on this</p> <p>8 side.</p> <p>9 Q. In other words, it's circumstantial, that</p> <p>10 is the result of a levator avulsion, the collapsed</p> <p>11 vagina, not the avulsion itself, that's what we're</p> <p>12 looking at?</p> <p>13 A. Yeah, right, the vagina is supported at</p> <p>14 the level of the arcus tendineus fascia pelvis and the</p> <p>15 periurethral area, as I explained on my report, it's</p> <p>16 supported by this arrangement of the levator muscle,</p> <p>17 the arcus tendineus fascia pelvis and the pubourethral</p> <p>18 ligament.</p> <p>19 Q. And the collapsing of the left side of</p> <p>20 the vaginal canal, or the vaginal wall --</p> <p>21 A. The vaginal wall.</p> <p>22 Q. -- is, is your evidence of a levator</p> <p>23 avulsion in this image?</p> <p>24 A. In this image, yes.</p> <p>25 Q. Okay. Anything else in Exhibit 18 that</p>	<p>1 urethra, the symphysis pubis, the obturator muscles,</p> <p>2 the adductor magnus and adductor longus muscle.</p> <p>3 Q. Okay. Now, does this image show us the</p> <p>4 levator avulsion?</p> <p>5 A. Yes.</p> <p>6 Q. Okay, and can you show us where?</p> <p>7 A. Right here.</p> <p>8 Q. Okay, and just put an arrow out here and</p> <p>9 say levator avulsion. All right, and this was ordered</p> <p>10 by Dr. Zimmern also, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Okay, and where in that circle you've</p> <p>13 drawn is the levator avulsion?</p> <p>14 A. Well, you can see the muscle going all</p> <p>15 the way up, and its insertion on the pubis right here,</p> <p>16 and you see that this insertion doesn't go up. If you</p> <p>17 put a line, you put the insertion right here, this is</p> <p>18 the insertion and this is the long insertion.</p> <p>19 Q. When you say this is the long insertion,</p> <p>20 you mean this black triangle here?</p> <p>21 A. No, the muscle right here. All this</p> <p>22 here. And this is, this is all your levator.</p> <p>23 Q. Okay. Now, have you ever seen a, an</p> <p>24 image of an actual levator avulsion?</p> <p>25 A. Yes.</p>
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<p>1 would indicate a levator avulsion other than what you</p> <p>2 described for us, Doctor?</p> <p>3 A. Just in this image, which is a pure</p> <p>4 image, it is done at 3D, this is a pure image obtained</p> <p>5 on the ultrasound.</p> <p>6 Q. And Dr. Zimmern ordered this and looked</p> <p>7 at this, did he not?</p> <p>8 A. I don't know if he looked at it.</p> <p>9 Q. Well, he said he looked at it, didn't he?</p> <p>10 A. I, I think that he testified that he</p> <p>11 looks at MRIs on Friday mornings, but I don't recall</p> <p>12 him saying that he looked at the ultrasound.</p> <p>13 Q. And if he did look at this ultrasound and</p> <p>14 didn't see what you saw, Dr. Zimmern just missed this</p> <p>15 levator avulsion that you've shown us, correct, or the</p> <p>16 result of the levator avulsion, that is the collapsed</p> <p>17 left side of the vaginal wall?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Let's look at 19. Does this help</p> <p>20 us, or help you give an opinion that there was a</p> <p>21 levator avulsion in Jennifer?</p> <p>22 A. Yes, there's, there's the levator --</p> <p>23 Q. First of all, what are we looking at?</p> <p>24 A. We're looking at an MRI image at the</p> <p>25 level of the urethra showing the levator muscles, the</p>	<p>1 Q. Did you pull one out as a comparator to</p> <p>2 see if it looked like what you've got here for</p> <p>3 Jennifer?</p> <p>4 A. Yes.</p> <p>5 Q. Okay, do you have that with you?</p> <p>6 A. Yes. These are images.</p> <p>7 Q. First of all, let's mark this and make</p> <p>8 sure we know what we're looking at. So I'm going to</p> <p>9 mark as Exhibit 21 ultrasound imaging of the pelvic</p> <p>10 floor, part 2, three-dimensional or volume imaging in</p> <p>11 the, published online, Ultrasound Obstetrical</p> <p>12 Gynecology, 2004.</p> <p>13 (Plaintiff's Exhibit No. 21 was marked</p> <p>14 for identification.)</p> <p>15 BY MR. FREESE:</p> <p>16 Q. Is that correct?</p> <p>17 A. Yes.</p> <p>18 Q. And you turned us to page 620, and Dietz</p> <p>19 I guess is the author?</p> <p>20 A. Yes.</p> <p>21 Q. And are you actually looking at the book</p> <p>22 itself?</p> <p>23 A. I'm also looking at the book, because I</p> <p>24 believe I have seen also pictures of a levator</p> <p>25 avulsion, but we can just go by the, with the paper.</p>

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<p>1 Q. This is a chapter in a textbook?</p> <p>2 A. No, that's a publication. That's a</p> <p>3 reviewed article.</p> <p>4 Q. This is not the published version of</p> <p>5 this?</p> <p>6 A. No.</p> <p>7 Q. Okay. Let's deal with this first and</p> <p>8 then we'll get to that.</p> <p>9 A. That is my ultrasound book.</p> <p>10 Q. So, Exhibit 21, page 620, is</p> <p>11 demonstrating what a levator avulsion looks like?</p> <p>12 A. Right, this is the magnetic resonance</p> <p>13 image of a levator avulsion, there you see the levator</p> <p>14 inserting completely up here, and in here it doesn't</p> <p>15 insert in a similar way that is happening here.</p> <p>16 Q. Okay. So you're comparing Exhibit 19</p> <p>17 with image A on page 620 of Exhibit 21?</p> <p>18 A. Yes, the only thing is that the levator</p> <p>19 avulsion on this article is on the right, and here the</p> <p>20 levator avulsion is on the left.</p> <p>21 Q. Okay, but just so I can orient myself,</p> <p>22 this, is this black spot right here on the right, is</p> <p>23 that the avulsion?</p> <p>24 A. No, there's no avulsion on this side.</p> <p>25 There's avulsion on this side. You see the muscle</p>	<p>1 six CDs for Jennifer Ramirez, and, with facilities are</p> <p>2 listed as the University of Texas Southwestern Medical</p> <p>3 Center, it's got the date it was obtained, correct?</p> <p>4 A. Yes, that's the date of service.</p> <p>5 Q. Northeast Methodist Hospital, obtained</p> <p>6 10/23/14. What is that?</p> <p>7 A. I can't remember what it is.</p> <p>8 Q. Let's just mark all six of them. This is</p> <p>9 20. I know I'm going out of order.</p> <p>10 (Plaintiff's Exhibit No. 20 was marked</p> <p>11 for identification and was retained by</p> <p>12 Plaintiff's attorneys.)</p> <p>13 BY MR. FREESE:</p> <p>14 Q. Will these, these are images of the</p> <p>15 ultrasound and MRI of Jennifer?</p> <p>16 A. Yes.</p> <p>17 Q. And we can look at Exhibit 20 and see</p> <p>18 this levator avulsion that you've been discussing in</p> <p>19 these other exhibits?</p> <p>20 A. Yes, the other two, two images that</p> <p>21 aren't as representative as this one.</p> <p>22 Q. There are two other images that are</p> <p>23 representative of what you've already marked?</p> <p>24 A. That aren't as representative as this</p> <p>25 one.</p>
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<p>1 coming underneath and then it goes up to here, and this</p> <p>2 is where it avulses from.</p> <p>3 Q. So, the avulsion is on the left lower</p> <p>4 quadrant of Exhibit A?</p> <p>5 A. Yeah, but this corresponds to the right</p> <p>6 side of this image.</p> <p>7 Q. So you can you draw a circle around the</p> <p>8 avulsion in, on page 620-A of Exhibit 21?</p> <p>9 A. Yes.</p> <p>10 Q. And then just write arrow, avulsion. And</p> <p>11 what you're saying is that right side avulsion in this</p> <p>12 Exhibit 21 is the same thing that you're seeing in</p> <p>13 Jennifer's MRI in Exhibit 19?</p> <p>14 A. Yes, it's the loss of continuity of the</p> <p>15 left levator muscle.</p> <p>16 Q. Okay. Now, you said that you have, you</p> <p>17 have the CD, you have the actual film itself?</p> <p>18 A. Yes, I brought those CDs to, as exhibits</p> <p>19 today because I was required on the order.</p> <p>20 Q. Right. I just want to slap an Exhibit</p> <p>21 sticker on it.</p> <p>22 A. I don't know which one exactly it is. I</p> <p>23 have a group of them here.</p> <p>24 Q. All right, let me stamp all of them.</p> <p>25 So, what you've handed me, Doctor, are</p>	<p>1 Q. Is there anything better to show the</p> <p>2 avulsion, other what we've already marked?</p> <p>3 A. There are two other images that don't</p> <p>4 have the arrows in the middle.</p> <p>5 Q. Do they make it any easier to see the</p> <p>6 avulsion?</p> <p>7 A. No, it essentially confirms this one.</p> <p>8 Q. Have you now identified everything that</p> <p>9 supports your opinion that Jennifer suffered a levator</p> <p>10 avulsion?</p> <p>11 A. This, and the final one that I marked was</p> <p>12 my physical exam.</p> <p>13 Q. Okay, and we're going to get to that.</p> <p>14 Well, we'll get to it right now.</p> <p>15 Now, when did you first diagnose Jennifer</p> <p>16 with a levator avulsion?</p> <p>17 A. When I examined her.</p> <p>18 Q. Okay. That was when you saw her in</p> <p>19 person?</p> <p>20 A. Yes.</p> <p>21 (Plaintiff's Exhibit No. 22 was marked</p> <p>22 for identification.)</p> <p>23 BY MR. FREESE:</p> <p>24 Q. Okay. I'm going to show you Exhibit 22.</p> <p>25 Is this your record of your exam of Jennifer?</p>

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<p>1 A. Yes.</p> <p>2 Q. Okay. Would you look at your IME,</p> <p>3 Doctor, and tell me where you diagnosed a levator</p> <p>4 avulsion in here?</p> <p>5 A. I, I confirmed my, my suspicion of a</p> <p>6 levator avulsion, my clinical suspicion, I should say,</p> <p>7 my clinical suspicion of a levator avulsion, and I</p> <p>8 described when I placed, I examined her and I placed a</p> <p>9 Q-tip in her vagina, right in the middle, and I saw</p> <p>10 that this, that this Q-tip deviated from one side to</p> <p>11 the, to the, to the upper side. I asked her to do a</p> <p>12 valsalva maneuver to push, and I saw how this Q-tip</p> <p>13 deviated, and this is in, I decided to do it this way</p> <p>14 because it's a way in which it would not be painful to</p> <p>15 her, it would just measure the axis, and this is, this</p> <p>16 correlates with the description by Dr. Kelly Scott of</p> <p>17 the right side being higher than the left side.</p> <p>18 Q. Doctor, am I correct that, that when you</p> <p>19 do this IME, you were trying to write down all the most</p> <p>20 important findings that you were making</p> <p>21 contemporaneously with that examination?</p> <p>22 A. No, I'm not writing while I'm examining</p> <p>23 her.</p> <p>24 Q. I know, but when you write your report</p> <p>25 it's fairly contemporaneous, right, so you remember</p>	<p>1 exam.</p> <p>2 Q. Would you show me where you diagnosed</p> <p>3 levator avulsion in your IME?</p> <p>4 A. Well, the diagnosis of levator avulsion</p> <p>5 is a mix of clinical and it's a mix of the x-rays and</p> <p>6 of the physical findings.</p> <p>7 Q. Move to strike. Dr. Sepulveda, would you</p> <p>8 show me in your IME report where you diagnosed Jennifer</p> <p>9 with a levator avulsion?</p> <p>10 A. Yes, sir. It says Q-tip is deviated</p> <p>11 downward --</p> <p>12 Q. What page are you on, sir?</p> <p>13 A. On page 2 out of 4. Q-tip is deviated</p> <p>14 downward and to the left on the pelvic contraction,</p> <p>15 upward on relaxation.</p> <p>16 Q. Okay. Now, where does the word levator</p> <p>17 avulsion appear anywhere on there?</p> <p>18 A. Oh, this is a physical exam. I don't</p> <p>19 establish a diagnosis here.</p> <p>20 Q. Okay, well, am I correct that the phrase</p> <p>21 levator avulsion appears nowhere in your IME?</p> <p>22 A. You can say that, yes.</p> <p>23 Q. And, in fact, it's a critical medical</p> <p>24 conclusion of the entirety of your opinions, is it not?</p> <p>25 Because you think it caused a, a number of Jennifer's</p>
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<p>1 what you just did?</p> <p>2 A. Right, and I carry my computer.</p> <p>3 Q. Okay. Well, you did the exam on November</p> <p>4 12th, 2015, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And you signed the report on November</p> <p>7 23rd, 2015?</p> <p>8 A. That's when it's closed.</p> <p>9 Q. Okay. What I'm trying to get at is, you</p> <p>10 did this IME contemporaneously, or at or about the time</p> <p>11 you did the IME, you prepared the report, correct?</p> <p>12 A. Well, no, I examined her, I write down my</p> <p>13 physical exam, and then I, I go through all the other</p> <p>14 parts of the clinical history, and I close the</p> <p>15 encounter later on.</p> <p>16 Q. Okay. So, by the 23rd of November, 2015,</p> <p>17 you had completed this Exhibit Number 22, correct?</p> <p>18 A. Right, whenever it says that I closed the</p> <p>19 encounter, there's a time when it's entered and there's</p> <p>20 a time when it's closed.</p> <p>21 Q. And you were trying to record all the</p> <p>22 most important findings that you, all the most</p> <p>23 significant findings that you were discovering in the</p> <p>24 IME, correct?</p> <p>25 A. Yes, I do, I do record it on my physical</p>	<p>1 complications here, correct?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. Yes.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. Yet it appears nowhere in your IME, does</p> <p>6 it?</p> <p>7 A. No, it does not appear in my IME.</p> <p>8 Q. And you said you suspected it when you</p> <p>9 did your IME, correct?</p> <p>10 A. Yes.</p> <p>11 Q. You don't put anywhere in there that you</p> <p>12 suspected levator avulsion, do you?</p> <p>13 A. No, I just put the physical findings.</p> <p>14 Q. Well, you do more than that. Then you</p> <p>15 have assessments, do you not?</p> <p>16 A. Yes, sir.</p> <p>17 Q. Okay, let's go to the assessments.</p> <p>18 Hyperesthesia, what is that?</p> <p>19 A. That there is a heightened sensation.</p> <p>20 Q. Where?</p> <p>21 A. In the, in the vulva.</p> <p>22 Q. That's an assessment you made at the time</p> <p>23 you did the IME?</p> <p>24 A. Yes. That has a code.</p> <p>25 Q. Postprocedural adhesions of vagina, what</p>

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<p>1      is that?</p> <p>2      A. That is the tenderness that was felt on 3      the upper left of the vagina with my findings of this 4      tenderness being reproduced on palpation and being 5      correlated by Mrs. Ramirez as the pain that she 6      referred during intercourse.</p> <p>7      Q. And dyspareunia. You assessed 8      dyspareunia.</p> <p>9      A. Yes, dyspareunia is, can be a diagnosis 10     or it can be a description of a symptom.</p> <p>11     Q. Which one is it here?</p> <p>12     A. It's a description of a symptom because 13     we could not reproduce the actual activity that would 14     lead to dyspareunia.</p> <p>15     Q. Well, you have an assessment that she's 16     suffering dyspareunia, do you not?</p> <p>17     A. Yes, that's a description, yes.</p> <p>18     Q. So, you conclude that she was in fact 19     suffering dyspareunia.</p> <p>20     A. That's a diagnosis based on the symptoms.</p> <p>21     Q. And that's what you did?</p> <p>22     A. I have no, no reason to disregard her 23     symptoms when she's telling me that she had pain.</p> <p>24     Q. Okay, what are these codes here?</p> <p>25     A. These are the ICD-10 codes.</p>	<p>1      A. No, I informed Mrs. Ramirez that I would 2      forward this report to the attorneys and that it could 3      be available to her through her attorneys. Through 4      you.</p> <p>5      Q. You're saying on the day you performed 6      this IME, you suspected a levator avulsion, yet you 7      didn't report it in your IME?</p> <p>8      A. Yeah, I just recorded the physical 9      findings.</p> <p>10     Q. Correct?</p> <p>11     A. That's correct.</p> <p>12     Q. You didn't report any physical findings 13     that said she's got a levator avulsion?</p> <p>14     A. No, that's incorrect.</p> <p>15     Q. By word, you didn't record anything that 16     said levator avulsion.</p> <p>17     A. I did not write the word avulsion.</p> <p>18     Q. Dr. Sepulveda, we could look at this 19     document all day long and we won't find the phrase 20     levator avulsion anywhere in it, will we?</p> <p>21     A. No, you would not find avulsion in this 22     document.</p> <p>23     Q. And this document is the actual physical 24     examination of Jennifer, correct?</p> <p>25     A. That's the physical examination of Mrs.</p>
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<p>1      Q. Okay. Is there a code for a levator 2      avulsion?</p> <p>3      A. There's a, there's a code for avulsion of 4      a muscle, but it's not specifically related to the 5      levator.</p> <p>6      Q. Okay, but you didn't put down any 7      avulsion of any muscle as an assessment, did you?</p> <p>8      A. No.</p> <p>9      Q. How do you treat a levator avulsion?</p> <p>10     A. There's a -- it depends on what kind of 11     avulsion you have. It could be partial or it could be 12     total. The treatment of levator avulsion has been 13     described with the use of an implant, with a mesh that 14     actually establishes the, a bridge from the muscle to 15     the upper part of the pubis.</p> <p>16     Q. How would Jennifer go about treating this 17     levator avulsion?</p> <p>18     A. It's, it's a rehab, you try to compensate 19     with other muscles in that area.</p> <p>20     Q. You didn't put that in your treatment 21     here in your IME, did you?</p> <p>22     A. No, I'm not allowed to give 23     recommendations on an IME.</p> <p>24     Q. Did you tell Jennifer she had suffered a 25     levator avulsion at the IME?</p>	<p>1      Ramirez.</p> <p>2      Q. And the first time that your diagnosis of 3      levator avulsion appears is in your report that you 4      prepared in this case, correct?</p> <p>5      A. Yes.</p> <p>6      Q. The one we've been going over all day 7      long?</p> <p>8      A. Yes.</p> <p>9      Q. Which was signed ten days ago?</p> <p>10     A. Yes.</p> <p>11     Q. That's the first record I've got of you 12     finding a diagnosis of levator avulsion in Jennifer 13     Ramirez was March 23rd, 2016?</p> <p>14     A. Yes, if you say that's the first one, 15     yes.</p> <p>16     Q. I'm asking you, did you report levator 17     avulsion to us before, as a diagnosis before March 18     23rd, 2016?</p> <p>19     MS. GALLAGHER: Form.</p> <p>20     A. We have not communicated any other way.</p> <p>21     BY MR. FREESE:</p> <p>22     Q. So, the answer is the first time that you 23     have put yourself on record as saying that Jennifer 24     suffered a levator avulsion was ten days ago?</p> <p>25     A. Yes, sir.</p>

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<p>1 MS. GALLAGHER: Object to form.      2 BY MR. FREESE:      3 Q. Four weeks before trial in this case.      4 Three weeks before trial.      5 MS. GALLAGHER: Object to form.      6 A. Yes.      7 BY MR. FREESE:      8 Q. And I won't find that anywhere in your      9 disclosures, will I?      10 A. On the --      11 Q. About opinions you're going to render,      12 what you're going to testify about. The only place I'm      13 going to find levator avulsion in any report you did is      14 the one that's dated March 23rd, 2016?      15 MS. GALLAGHER: Object to form.      16 A. Yes, my report. My opinion.      17 BY MR. FREESE:      18 Q. Okay. Now, you say in your report that      19 the, that the findings of Dr. Graham were the result of      20 a damaged and relaxed pelvic floor, three previous      21 vaginal deliveries, and the granulation tissue from a      22 hysterectomy.      23 A. Yes.      24 Q. Did I read that correctly?      25 A. Yes, sir.</p>	<p>1 relaxed pelvic floor as any basis for Jennifer's      2 injuries?      3 A. No, he does not describe that.      4 Q. Do you agree with me that he does not      5 mention three previous vaginal deliveries in any manner      6 in his operative report as a basis for Jennifer's      7 injuries?      8 A. Dr. Graham does not describe that.      9 Q. And he does not mention granulation      10 tissue from a hysterectomy in any way as causing      11 Jennifer's complications, correct?      12 A. He does describe that the granulation      13 tissue was causing the bleeding.      14 Q. Well, here's his operative report. Where      15 does it say the granulation causes bleeding, sir?      16 A. I then examined vaginally and saw two      17 areas of granulation tissue at the cuff and I excised      18 one portion and closed it with a chromic stitch. There      19 was a smaller area of granulation tissue on the right      20 lateral side of the healing cuff, which I cauterized.      21 That is the cause of the bleeding.      22 Q. Does Dr. Graham say it's the cause of the      23 bleeding?      24 A. Well, he's not saying, but it's quite      25 evident that he excised that tissue because it causes</p>
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<p>1 Q. I'm a little unclear, Dr. Sepulveda.      2 What findings of Dr. Graham were the result of a      3 damaged and relaxed pelvic floor, three previous      4 vaginal deliveries and the granulation tissue from a      5 hysterectomy?      6 A. I think this is what we have those pages      7 that are -- let's look through it. I've got it here.      8 Q. Okay. You say in your report, quote,      9 "The findings described by Dr. Graham were the result      10 of a damaged and relaxed pelvic floor, three previous      11 vaginal deliveries, and the granulation tissue from a      12 hysterectomy," correct?      13 A. And I also contributed with a lack of      14 fibromuscular tissue.      15 Q. Let's stop with that sentence. We've      16 already looked at Dr. Graham's operative reports. He      17 doesn't mention anything about a damaged and relaxed      18 pelvic floor, does he, as causing any of her symptoms,      19 does he?      20 A. No, my opinion is an interpretation of      21 the findings that he had.      22 Q. Okay, well, let's bypass the      23 interpretation and let's see what he actually said,      24 okay? Do you agree with me that in Dr. Graham's      25 operative report, he does not mention a damaged or</p>	<p>1 bleeding.      2 Q. Okay, does his report say that any      3 bleeding was caused by the granulation of the      4 hysterectomy of the cuff?      5 A. Well, he has it as vaginal bleeding and      6 he has the granulation tissue that he excises.      7 Q. Where does he have that, sir?      8 A. Vaginal bleeding, and then he ties it up      9 here with granulation tissue that he removed.      10 Q. Yeah, but it says postoperative      11 diagnosis, pelvic pain from transobdurator tape, comma,      12 vaginal bleeding. So, he doesn't say that vaginal      13 bleeding is being caused by the hysterectomy, he says      14 being caused by the transobdurator tape.      15 MS. GALLAGHER: Object to form.      16 A. No, I don't think that -- you might want      17 to ask Dr. Graham about that, because I don't see him      18 describing the transobdurator tape as the cause of      19 bleeding. No, that would be an inaccurate      20 characterization of his report.      21 BY MR. FREESE:      22 Q. Well, do you agree that the entirety of      23 his postoperative diagnosis is pelvic pain from      24 transobdurator tape, comma, vaginal bleeding? Did I      25 read that correctly, sir?</p>

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<p>1        A. Yes.</p> <p>2        Q. Does he say anywhere in the report that 3 the bleeding was because of granulation at the vaginal 4 cuff?</p> <p>5        A. No, he just excised the granulation 6 tissue.</p> <p>7        Q. Now, I don't want to talk about bleeding. 8 I want to talk about pain for a second, okay? The 9 findings described by Dr. Graham, what findings are you 10 referencing in your report?</p> <p>11      A. The, the granulation tissue.</p> <p>12      Q. Okay. And you --</p> <p>13      A. And the, the bowstringing.</p> <p>14      Q. And you just ignore his conclusion that 15 the tape was causing the pain?</p> <p>16      MS. GALLAGHER: Object to form.</p> <p>17      A. Yeah, I'm not, I'm not following this 18 one.</p> <p>19      BY MR. FREESE:</p> <p>20      Q. You're saying the findings of Dr. Graham, 21 well, the finding of Dr. Graham is the pain is from the 22 transobturator tape. That's his finding, is it not?</p> <p>23      MS. GALLAGHER: Object to form.</p> <p>24      A. That's not a finding. That's his 25 conclusion. That's his diagnostic impression.</p>	<p>1        the postop diagnosis.</p> <p>2        Q. Do you agree with me that a postoperative 3 diagnosis is a finding?</p> <p>4        A. No, a postoperative diagnosis is 5 different from a finding. You make a diagnosis based 6 on your findings. What this postoperative diagnosis 7 does not list is the fact that he found granulation 8 tissue and he excised it.</p> <p>9        Q. Yes, it does. It talks about the 10 granulation tissue in the postoperative report.</p> <p>11      A. But it's not listed on the postoperative 12 diagnosis.</p> <p>13      Q. Here's what I'm trying to figure out, 14 Doctor. You say the findings of Dr. Graham. Do you 15 agree with me that pelvic pain from transobturator tape 16 is a finding of Dr. Graham's?</p> <p>17      A. Pelvic pain from transobturator tape is 18 his diagnostic impression.</p> <p>19      Q. Doctor, is Dr. Graham's diagnostic -- is 20 Dr. Graham's postoperative diagnosis of pelvic pain 21 from transobturator tape a finding? Yes or no?</p> <p>22      A. No, that's his diagnosis.</p> <p>23      Q. So, he did not find the transobturator 24 tape was causing the pain?</p> <p>25      A. No, that's not a finding. That's not an</p>
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<p>1      BY MR. FREESE:</p> <p>2      Q. What's the difference between a 3 conclusion and a diagnostic impression? Let me back 4 up. What is the difference between a postoperative 5 diagnosis and a conclusion?</p> <p>6      A. The postoperative diagnosis is your 7 impression of what --</p> <p>8      Q. That's not a conclusion?</p> <p>9      A. That, that's not a diagnostic conclusion.</p> <p>10     Q. So, a postoperative diagnosis is not a 11 diagnostic conclusion?</p> <p>12     A. No.</p> <p>13     Q. Did I hear you correctly, did you say 14 that?</p> <p>15     A. Yeah, I just said that, I just said 16 exactly that.</p> <p>17     Q. Okay, your diagnosis --</p> <p>18     A. I just said exactly that.</p> <p>19     Q. Doctor, we've got to slow down here. 20 It's your testimony that a postoperative diagnosis is a 21 not a diagnostic conclusion?</p> <p>22     A. A postoperative diagnosis in this 23 specific scenario is not his postoperative conclusion, 24 because Dr. Graham found granulation tissue on his 25 description of the report, and he does not list that in</p>	<p>1      objective finding.</p> <p>2      Q. Is it a subjective finding?</p> <p>3      A. Yeah, that's his clinical impression.</p> <p>4      Q. I'm trying to figure out, Doctor, why you 5 say all these things are the findings described by Dr. 6 Graham when his operative report doesn't say any of 7 them. The one thing he does say is that the pain is 8 caused by the transobturator tape, and you don't even 9 list it as a finding by Dr. Graham.</p> <p>10     MS. GALLAGHER: Object to form.</p> <p>11     BY MR. FREESE:</p> <p>12     Q. You understand my curiosity with that?</p> <p>13     A. So, what is the question?</p> <p>14     Q. The question is, you're saying the 15 findings described by Dr. Graham were the result of, 16 and you rattle off three things, none of which is in 17 Dr. Graham's operative report, but the one thing that 18 is, that is the pain is being caused by transobturator 19 tape is not even listed in your findings.</p> <p>20     MS. GALLAGHER: Object to form.</p> <p>21     A. I'm giving a diagnostic impression here.</p> <p>22     BY MR. FREESE:</p> <p>23     Q. Am I accurately stating it?</p> <p>24     A. No, I did not list in my diagnostic 25 impression the finding from Dr. Graham, or the</p>

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<p>1 diagnosis as you say, the diagnosis that Dr. Graham 2 made.</p> <p>3 Q. But you're attempting to report what Dr. 4 Graham's findings were, correct? You're reporting Dr. 5 Graham's findings, are you not?</p> <p>6 A. Yes, it's --</p> <p>7 Q. Stop. You're reporting Dr. Graham's 8 findings, correct?</p> <p>9 MS. GALLAGHER: Let him finish his 10 answer.</p> <p>11 MR. FREESE: It's a yes or no question.</p> <p>12 MS. GALLAGHER: Okay, you cut off the 13 explanation. Go ahead.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. You are reporting Dr. Graham's findings 16 in your expert report, are you not, Dr. Sepulveda?</p> <p>17 A. I am reporting my impression of the 18 operative report that I reached from Dr. Graham.</p> <p>19 Q. And your impression excludes the one 20 thing that he says caused the pain, which was 21 transobturator tape, correct?</p> <p>22 A. Yes, because I don't believe that a 23 transobturator tape is causing the pain.</p> <p>24 Q. But your report isn't giving your 25 opinion; you're trying to report what Dr. Graham's</p>	<p>1 anywhere in his operative report, are they?</p> <p>2 A. No, the findings described by Dr. Graham, 3 which is the bowstringing, which is the tape that he 4 was able to feel, and that's exactly what I'm referring 5 to, were the result of the relaxed pelvic floor.</p> <p>6 That's my explanation on this document.</p> <p>7 Q. But that --</p> <p>8 A. I haven't finished answering your 9 question. The findings, the findings described by Dr. 10 Graham specifically, the bowstringing and the sensation 11 of the tape on the vagina, which was not without being 12 exposed, is a result of all this, of all these 13 problems, the damaged and relaxed vaginal floor, three 14 previous vaginal deliveries, and the findings that he 15 described of granulation tissue is exactly what he 16 describes.</p> <p>17 Q. Except he doesn't say anything near what 18 you're saying, does he?</p> <p>19 MS. GALLAGHER: Object to form.</p> <p>20 BY MR. FREESE:</p> <p>21 Q. He doesn't conclude anything like what 22 you concluded, does he?</p> <p>23 MS. GALLAGHER: Object to form.</p> <p>24 A. It's a, it's a different, it's a 25 different, it's a different description, because what</p>
<p style="text-align: center;">Page 251</p> <p>1 findings are, correct?</p> <p>2 A. I cannot report on Dr. Graham's findings. 3 Dr. Graham's findings are documented in his operative 4 report.</p> <p>5 Q. Which is inconsistent with what you're 6 saying his findings were.</p> <p>7 A. I say that the result of his findings are 8 in this explanation. This is what explains the result 9 of his findings.</p> <p>10 Q. Dr. Sepulveda, your quote, the findings 11 described by Dr. Graham, let's stop with that right 12 there, the findings described by Dr. Graham. You agree 13 with me those findings are contained in Exhibit 16, are 14 they not?</p> <p>15 A. Repeat that question.</p> <p>16 Q. Yes. The findings of Dr. Graham are 17 contained in Exhibit 16, are they not?</p> <p>18 A. You keep, you keep calling the, you keep 19 calling the diagnosis as findings, and the --</p> <p>20 Q. Well -- okay, go ahead.</p> <p>21 A. And the findings are in the body of the 22 report. This report speaks for itself on the body of 23 the report.</p> <p>24 Q. Let me put it this way. The findings 25 that you have recorded here of Dr. Graham, they're not</p>	<p style="text-align: center;">Page 253</p> <p>1 he is saying is that his impression is that the tape is 2 causing the pain. What the findings that I am talking 3 about is about the bowstringing of the tape.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. And he found the bowstringing, right?</p> <p>6 A. He did describe that before surgery.</p> <p>7 Q. And he did not believe that the 8 bowstringing had anything to do with the avulsed 9 levator muscle, did he?</p> <p>10 MS. GALLAGHER: Object to form.</p> <p>11 A. No, he did not contribute to that, he did 12 not describe that.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. You did.</p> <p>15 A. I did.</p> <p>16 Q. Dr. Sepulveda, have you looked at any of 17 the manufacturing defect reports that Ethicon generated 18 off of the lot that Jennifer Ramirez's mesh came from, 19 that her sling came from?</p> <p>20 A. No, I have not, I have not seen 21 specifically the manufacturing defects from that 22 specific lot.</p> <p>23 Q. Have you investigated that?</p> <p>24 A. I, I did see it on the TVTO company 25 documents, I saw a picture of, of particles in one of</p>

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<p>1 the, one of the slings.</p> <p>2 Q. You think it was simply one sling that 3 was suffering these particle loss problems?</p> <p>4 MS. GALLAGHER: Form.</p> <p>5 A. I don't know how many of them were, were 6 reported.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. Well, what if it was one versus a 9 hundred, would that make a difference to you?</p> <p>10 A. Well, you just asked me a question if I 11 knew how many of them, and my answer is no, I don't 12 know how many. One or a hundred, I don't know.</p> <p>13 Q. You're trying to give an opinion that 14 there was not particle loss on Jennifer's sling, are 15 you not?</p> <p>16 A. Yes.</p> <p>17 Q. Yet you have no idea how many slings from 18 that lot were suffering excessive particle loss, do 19 you?</p> <p>20 A. I can only base my opinion on what the 21 implanter described, and the implanter described there 22 was no particle loss.</p> <p>23 Q. He did not see any?</p> <p>24 A. He did not see particle loss.</p> <p>25 Q. And, therefore, you concluded there was</p>	<p>1 correct? Her TVTO sling?</p> <p>2 A. I am aware that there were 3 communications, which I have read through, but since 4 most of my input has been concentrated on this, I 5 cannot recall. On the, I should have to say on the 6 clinical summary and the opinion, I cannot recall of 7 one specific article that I can pull to you and show.</p> <p>8 Q. Will I find it in the TVTO company 9 documents?</p> <p>10 A. It might be there.</p> <p>11 Q. Well, you say that reported particles in 12 a blister pack from one of 992 devices in the same lot.</p> <p>13 A. I probably read it in the company 14 documents.</p> <p>15 Q. Okay, and you believe that they only 16 found one pack with particles in it?</p> <p>17 A. That's in my -- where is it in my report?</p> <p>18 Q. Let me just short circuit this. You're 19 not offering any opinions, good or bad, about 20 manufacturing defects in this case, are you?</p> <p>21 MS. GALLAGHER: Object to form.</p> <p>22 A. It depends on what area of manufacturing. I can tell you that if it was manufactured one way or the other, I cannot give an opinion on it, because I don't manufacture slings, of course. I want to stay</p>
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<p>1 none?</p> <p>2 A. He is in a privileged position to, to 3 judge if there are particles.</p> <p>4 Q. Just answer my question. Just because 5 Dr. Reyes didn't report it, you concluded there was 6 none in Jennifer, is that correct?</p> <p>7 A. I can safely conclude because the 8 implanter did not see any particle loss, that there are 9 no, no particles.</p> <p>10 Q. And you are not here to give an opinion 11 whether or not that lot was defectively manufactured in 12 contravention of Ethicon's standards, am I correct?</p> <p>13 MS. GALLAGHER: Object to form.</p> <p>14 A. I don't know if they define -- I do know, 15 I do know that they define one specific standard, which 16 was a number of particles which I cannot recall at this 17 time.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. It was five.</p> <p>20 A. But I can tell you that if there's, if 21 it's one, five or ten, the best person to say that is 22 Dr. Reyes.</p> <p>23 Q. Okay, well, that's not my question. You 24 have not investigated what Ethicon did in reviewing the 25 lot of mesh that went into Jennifer's sling, am I</p>	<p>1 truthful to what I testify on, but as an issue of the 2 particle loss, the implanter is the best person to see.</p> <p>3 BY MR. FREESE:</p> <p>4 Q. I understand that, but you have not 5 investigated informed, scientifically valid opinions 6 whether or not the manufacturing processes were 7 followed according to the manufacturer's specifications 8 in this lot that included Jennifer's sling, am I 9 correct?</p> <p>10 A. I have not done an investigation on it, 11 no.</p> <p>12 Q. I'm going to page 61. I don't know what 13 page it is on your report. It starts off with Ms. 14 Ramirez's source.</p> <p>15 A. Yes.</p> <p>16 Q. You say Mr. Ramirez's source of periodic 17 dyspareunia, if present before Dr. Zimmern's surgery, 18 was caused by abnormal healing into the vaginal 19 excision from the hysterectomy, unrelated to the TVTO. 20 Additionally, after the hysterectomy, the avulsed 21 levator muscle on the left resulted in the upper part 22 of the vagina becoming detached and the vaginal vault 23 scarred which resulted in additional complaints of 24 dyspareunia. Do you see that?</p> <p>25 A. Yes.</p>

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<p>1       Q. So, let's go to the next paragraph, the 2 diagnosis --</p> <p>3       A. Here, yeah, Mrs. Ramirez's source, yeah, 4 I got it.</p> <p>5       Q. And we've already talked about that, 6 right? You've given me all your opinions about the 7 avulsion of the levator muscle on the left resulted in 8 the upper part of the vagina becoming detached and the 9 vaginal vault scarred?</p> <p>10      A. It is my opinion to a reasonable degree 11 of certainty that Mrs. Ramirez's source of periodic 12 dyspareunia, if present before Dr. Zimmern's surgery, 13 was caused by abnormal healing into the vaginal 14 incision from the hysterectomy unrelated to the TVTO.</p> <p>15      Q. Okay, so let's stop. You're the only 16 doctor that's made that diagnosis, correct?</p> <p>17      A. No, that's, there was, there was a 18 diagnosis by Dr. Atkerson about dyspareunia on deep 19 penetration.</p> <p>20      Q. But my question, Dr. Sepulveda, you were 21 the only doctor that has said that her periodic 22 dyspareunia was caused by abnormal healing from the 23 hysterectomy, correct?</p> <p>24      A. Yes, that is my opinion.</p> <p>25      Q. And you're the only one that holds that</p>	<p>1       Q. And you would agree with me that you're 2 on the only doctor that has that opinion, correct?</p> <p>3       A. Yes, I am the only one that has given 4 that opinion so far, to my knowledge, yes.</p> <p>5       Q. And you're saying that her levator 6 avulsion is causing in part or whole her dyspareunia?</p> <p>7       A. No, I think that her dyspareunia is 8 caused also by the hysterectomy.</p> <p>9       Q. I understand. I said in part.</p> <p>10      A. Well, levator avulsion by itself may be a 11 less frequent cause of dyspareunia than a hysterectomy.</p> <p>12      Q. I'm not quibbling with you, Doctor. You 13 believe that the avulsion of the levator muscle is one 14 of the things that may be causing her dyspareunia?</p> <p>15      A. It is a predisposing factor to it.</p> <p>16      Q. Okay, and you are the only doctor that 17 has expressed that diagnosis, correct?</p> <p>18      A. That is correct.</p> <p>19      Q. Does an avulsion of the levator muscle 20 cause scarring?</p> <p>21      A. Yeah, there's a scar actually on the 22 detached muscle.</p> <p>23      Q. And you've identified it in your 24 examination?</p> <p>25      A. Yes, that was described on this area with</p>
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<p>1       opinion?</p> <p>2       MS. GALLAGHER: Object to form.</p> <p>3       A. I'm the one giving that opinion, yes.</p> <p>4 BY MR. FREESE:</p> <p>5       Q. But no treating physician of Jennifer 6 holds that opinion, correct?</p> <p>7       MS. GALLAGHER: Object to form.</p> <p>8       A. No, no treating physician is holding that 9 opinion.</p> <p>10      BY MR. FREESE:</p> <p>11      Q. Additionally, after the hysterectomy, the 12 avulsed levator muscle on the left resulted in the 13 upper part of the vagina becoming detached and the 14 vaginal vault scarred which resulted in additional 15 complaints of dyspareunia. Do you see that?</p> <p>16      A. That is my theory of how this happened.</p> <p>17      Q. I understand, and your theory is that in 18 addition to the hysterectomy, the avulsion of the 19 levator muscle is also contributing or causing her 20 dyspareunia, correct?</p> <p>21      A. Yes, I believe there's a complex etiology 22 here in which the predisposing factor was an avulsed 23 levator, the lack of support at the pubocervical fascia 24 produced this, this vaginal wall to come down and it 25 allowed for the bowstringing to be felt.</p>	<p>1       fibrotic tissue.</p> <p>2       Q. You're saying it was described by you?</p> <p>3       A. No, it was described I believe on the MRI 4 report.</p> <p>5       Q. But not as a result of a levator 6 avulsion?</p> <p>7       A. No, not as a result of a levator 8 avulsion.</p> <p>9       Q. Does anyone say that a levator avulsion 10 caused scarring other than you?</p> <p>11      A. No, it's, if you detach a muscle, as you 12 would any muscle that you would detach from its 13 attachment, it will form a scar.</p> <p>14      Q. Has anyone said that scarring occurred in 15 Jennifer's pelvis because of a levator avulsion?</p> <p>16      A. No.</p> <p>17      Q. Okay. Let's drop down. You see where it 18 says it's my opinion to a reasonable degree of medical 19 probability and certainty that the operation performed 20 by Dr. Zimmern was not medically necessary or 21 appropriate?</p> <p>22      A. Yes.</p> <p>23      Q. I guess we can agree that, that opinion 24 is that Dr. Zimmern has committed medical malpractice, 25 correct?</p>

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<p>1       A. Yes.</p> <p>2       Q. Because performing any medical procedure</p> <p>3       that's not medically necessary is by definition</p> <p>4       malpractice, is it not?</p> <p>5       A. If it leads to the pains that the patient</p> <p>6       has, yes.</p> <p>7       Q. Any surgery has pain, does it not?</p> <p>8       A. Every surgery has a risk for pain.</p> <p>9       Q. And any unnecessary surgery deliberately</p> <p>10      done is malpractice, correct?</p> <p>11      A. I don't say it was deliberately done.</p> <p>12      I'm saying that it was unnecessary.</p> <p>13      Q. Well, Dr. Zimmern deliberately did the</p> <p>14      surgery, did he not?</p> <p>15      A. He performed the surgery. I don't know</p> <p>16      which state of mind he was when he did it.</p> <p>17      Q. Are you saying he didn't know he was</p> <p>18      performing surgery?</p> <p>19      MS. GALLAGHER: Object to form.</p> <p>20      A. I'm saying I don't know in which state of</p> <p>21      mind he was when he decided to do the surgery.</p> <p>22      BY MR. FREESE:</p> <p>23      Q. But you understand he intentionally did</p> <p>24      the surgery he intended to do?</p> <p>25      A. He intended to go and take the mesh out,</p>	<p>1       performed by Dr. Zimmern?</p> <p>2       A. Yes.</p> <p>3       Q. All right. I want you to explain in much</p> <p>4       detail how Dr. Zimmern's surgery caused the pudendal</p> <p>5       nerve injury, please, sir.</p> <p>6       A. The excision of, or the search for a</p> <p>7       sling that was nonexistent in the diagnostic studies</p> <p>8       led to a dissection that was extensive on that side, on</p> <p>9       the left side. That dissection showed that there was</p> <p>10      periurethral fat. Periurethral fat in the anatomic</p> <p>11      dissections is not a common finding. It is my opinion</p> <p>12      that the fat that was obtained on the dissection and</p> <p>13      described by Dr. Zimmern in his operative report comes</p> <p>14      from the ischioanal fossa.</p> <p>15      Q. Okay, the fat that he found in his</p> <p>16      surgery was actually ischioanal fossa?</p> <p>17      A. From the ischioanal fossa, yes.</p> <p>18      Q. What, what surgical instrument was he</p> <p>19      using that caused the pudendal nerve injury?</p> <p>20      A. It's just the dissection. You can go</p> <p>21      with your finger and do a dissection in that area, and</p> <p>22      that can produce an injury to the pudendal nerve.</p> <p>23      Q. What do you believe based on your review</p> <p>24      of the records? I mean, you're accusing the man of</p> <p>25      malpractice, so I'm just curious, did he do it with his</p>
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<p>1       yes.</p> <p>2       Q. And it's your opinion that that was</p> <p>3       medically unnecessary?</p> <p>4       A. That's my opinion.</p> <p>5       Q. And that surgery would have been a</p> <p>6       violation of the standard of care?</p> <p>7       A. That is below the standard of care based</p> <p>8       on the symptoms that the patient has had.</p> <p>9       Q. And you believe that Dr. Zimmern, in</p> <p>10      doing this surgery, injured Jennifer's pudendal nerve,</p> <p>11      correct?</p> <p>12      A. Yes.</p> <p>13      Q. I want you to describe for me -- well,</p> <p>14      let's start with, so before Dr. Zimmern's surgery it's</p> <p>15      your opinion that Jennifer had not suffered a pudendal</p> <p>16      nerve injury, correct?</p> <p>17      A. That is correct.</p> <p>18      Q. You agree today that Jennifer does have a</p> <p>19      pudendal nerve injury?</p> <p>20      A. That has been demonstrated by the effects</p> <p>21      of the pudendal block, yes.</p> <p>22      Q. And it's an opinion you share, correct?</p> <p>23      A. Yes.</p> <p>24      Q. And it is your opinion that the sole</p> <p>25      cause of that pudendal nerve injury is the surgery</p>	<p>1       finger? Did he do it with a scalpel? Did he do it</p> <p>2       with scissors? What device did Dr. Zimmern use to</p> <p>3       cause this pudendal nerve injury?</p> <p>4       A. It's the dissection with the finger.</p> <p>5       Q. Okay. So a finger dissection caused the</p> <p>6       pudendal nerve injury.</p> <p>7       A. That's one of the factors, yes.</p> <p>8       Q. So, did he basically have to get his</p> <p>9       finger on the pudendal nerve?</p> <p>10      A. You know, what happens is, when you have</p> <p>11      a levator muscle that is detached and you already have</p> <p>12      an area that has been injured over time, you go into</p> <p>13      that area and there's very little muscle that you can</p> <p>14      feel. You're not actually looking at it, you're</p> <p>15      actually feeling for it. So, when you do all this, all</p> <p>16      this dissection, you injure the area, because this is</p> <p>17      not a pudendal nerve injury that has provoked, as many</p> <p>18      of your, as more than one of your experts has said, has</p> <p>19      provoked anal incontinence or has provoked urinary</p> <p>20      incontinence. This is an irritation to the pudendal</p> <p>21      nerve and this irritation to the pudendal nerve is what</p> <p>22      really ended up producing more pain. Before that,</p> <p>23      there was no injury on the dissection.</p> <p>24      Q. And --</p> <p>25      A. There was no injury to the nerve, I</p>

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<p>1 should have said, there was no injury to the nerve.      2 Q. How far did he dissect?      3 A. It's, by the time you get into the      4 ischioanal fossa, you have no levators protecting you.      5 All you have to do is two, three centimeters, and you      6 can ream that area.      7 Q. Does your opinion that Dr. Zimmern caused      8 a pudendal nerve injury depend on the accuracy of your      9 conclusion that she had a levator muscle avulsion?      10 A. It's a, it's a, it's a group of things      11 that lead me to believe that this was injured at that      12 point.      13 Q. Answer my question, Dr. Sepulveda. Does      14 your opinion that Dr. Zimmern caused a pudendal nerve      15 injury depend on the accuracy of your diagnosis that      16 she had an avulsion of her levator muscles?      17 MS. GALLAGHER: Object to form.      18 A. It depends, it relies on the history of      19 how a pudendal nerve is injured, it relies on the      20 dissection and a search for a sling that was not there,      21 a piece of sling that was not there. It also relies on      22 the MRI diagnosis of the muscle coming down, and it      23 relies on the, on the description of the, of the      24 operator.      25 BY MR. FREESE:</p>	<p>1 this morning, between the obturator space and the      2 obturator foramen. The obturator foramen, the way we      3 all know obturator foramen, the way it's described on      4 anatomic books is in the retropubic space. That's      5 different from the obturator space. We defined already      6 that the sling follows a trajectory which is 1.5 to 2.5      7 centimeters from the obturator foramen. The fact that      8 Mrs. Ramirez, I apologize myself for being graphic on      9 this, the fact that she was able to use a vibrator, it      10 virtually excludes a neurological injury. You cannot      11 have a neurological injury constant in that area and      12 vibrate and not feel pain with it, and the description      13 of her pain was on deep penetration. So it is my      14 conclusion that there was, if there was a mesh in      15 there, it's not around the nerve.      16 Q. And I appreciate you volunteering that,      17 but my question is, is there not residual mesh on her      18 left side in her obturator space today?      19 A. There's nothing in the periurethral. Dr.      20 Zimmern could not find mesh there.      21 Q. Not my question, Dr. Sepulveda. Is there      22 synthetic TVT, polypropylene, Prolene mesh in her      23 obturator space today?      24 A. In the --      25 Q. On the left side.</p>
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<p>1 Q. Dr. Sepulveda, what I'm trying to find      2 out, if we're proven that she did not have an avulsion      3 to the levator muscle, if the jury believes that she      4 does not have such a condition, would you still believe      5 that Dr. Zimmern's surgery caused the pudendal nerve      6 injury?      7 A. I see no other way to reach the pudendal      8 nerve but by getting into this space where the fat is.      9 Q. I understand, but what I'm saying is does      10 the avulsion have to exist in order to get the pudendal      11 nerve?      12 A. No, you can get a pudendal nerve injury      13 without an avulsion, but, again, as we have seen, there      14 are contributing factors and there are precipitating      15 factors and there are causative factors on here, and      16 this is not just about a black-and-white situation,      17 this is a situation in which the patient already showed      18 that she had a defect on the left side, there has been      19 pain before that, but there has not been neurological      20 pain.      21 Q. Move to strike. That's not responsive to      22 my question. Is it your testimony, Doctor, that the,      23 the mesh that extends into the, beyond the obturator      24 foramen is not still present in Jennifer today?      25 A. There's a definition, we defined that</p>	<p>1 A. On the obturator space, yes.      2 Q. So, the fact that Dr. Zimmern didn't find      3 any mesh on the left side doesn't mean there wasn't any      4 mesh on the left side. We both agree that even after      5 Dr. Graham's revision, there remained part of the TVTO      6 in her obturator space on her left side, correct?      7 A. There is mesh --      8 Q. Can we agree with that fact?      9 A. If we go to the left side, we need to      10 make a, a specific of looking at the left side, on the      11 medial aspect of the descending --      12 Q. The answer to my question is yes, Mr.      13 Freese, there's still remaining mesh on her left side,      14 on the other side of her obturator internus muscle,      15 right?      16 A. Yes.      17 Q. What alternative causes did you consider      18 and rule out for the injury to the pudendal nerve?      19 A. I find no other, no other things that      20 could have injured the pudendal nerve. Now we do know      21 that pudendal nerves can be injured in a variety of      22 procedures, but the onset of the pudendal nerve      23 symptoms after this, after this exploration is what      24 leads me to believe that it was during this surgery.      25 Q. Okay, so is the fact that you think she</p>

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<p style="text-align: center;">Page 270</p> <p>1 did not have evidence of nerve injury until after Dr. 2 Zimmern's surgery, that's the sole basis of your 3 opinion that you can rule out everything else?</p> <p>4 MS. GALLAGHER: Object to form.</p> <p>5 A. Yeah, there's no evidence of a pudendal nerve 6 injury before that surgery.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. Can synthetic mesh cause a pudendal nerve 9 injury?</p> <p>10 A. Not, not in that, not in that distance. For a pudendal nerve to be injured, it's, it would have 11 to be close to the pudendal nerve.</p> <p>12 Q. Dr. Sepulveda, can synthetic mesh cause a 13 pudendal nerve injury?</p> <p>14 A. Are you talking about a synthetic mesh 15 for a sling? Please clarify.</p> <p>16 Q. Yes, for a sling.</p> <p>17 A. A sling procedure. Yes, it has been 18 described to cause a pudendal nerve when the TVTO has 19 been improperly inserted.</p> <p>20 Q. So, only an improperly inserted sling can 21 cause a pudendal nerve injury?</p> <p>22 A. Yes.</p> <p>23 Q. And, so, did you consider maybe my 24 initial conclusion was wrong, maybe Dr. Reyes put it in</p>	<p style="text-align: center;">Page 272</p> <p>1 already today that you have never seen a pudendal nerve 2 injury caused by a revision to a sling, have you?</p> <p>3 A. I have not seen that either.</p> <p>4 Q. All right. But you know that meshes are 5 reported to cause pudendal nerve injuries, the mesh 6 themselves?</p> <p>7 A. That's, I think you're referring to, to 8 the, when it's placed on the side of the pudendal 9 nerve. I don't think that there's a report of a TVT, 10 or there are few reports based, there's a Paulson 11 study, which is a case report, there is the Masata, 12 which is also case reports, but there's no actual 13 cohort study that have measured pudendal nerve injuries 14 after a TVTO.</p> <p>15 Q. I'm just talking about synthetic meshes 16 generally. You don't think that mesh can cause -- 17 strike that.</p> <p>18 Your opinion, Dr. Sepulveda, is that an 19 improperly placed synthetic mesh can cause a pudendal 20 nerve injury?</p> <p>21 A. That would be the case, yes.</p> <p>22 Q. And you concluded that that wasn't the 23 case here because she wasn't showing, in your view, 24 signs of a pudendal nerve injury before Zimmern's 25 surgery, correct?</p>
<p style="text-align: center;">Page 271</p> <p>1 wrong, because an improperly inserted TVT can cause a 2 nerve injury; did you consider and exclude that as a 3 reason?</p> <p>4 A. No, because she did not have a pudendal 5 nerve symptomatology after Dr. Reyes' insertion of the 6 TVTO.</p> <p>7 Q. Well, she wasn't tested for it, was she? She had complaints of pain radiating down her leg, did 8 she not?</p> <p>9 A. The pain to the pudendal nerve, or injury 10 to the pudendal nerve is not characterized by pain 11 going down the legs producing tingling on the toes.</p> <p>12 Q. In other words, you're saying that a 13 pudendal nerve injury wouldn't mimic a sciatic nerve 14 injury?</p> <p>15 A. It does not mimic a sciatic nerve injury.</p> <p>16 Q. And you've never seen any literature that 17 says that?</p> <p>18 A. I think that if you, if you take the 19 pudendal nerve at the very end and you get an actual 20 pudendal transection, it could, it could have a 21 potential of mimicking, but once you establish a 22 diagnosis that it's traditional pudendal nerve, it's 23 separate from a sciatic nerve.</p> <p>24 Q. Let's be clear here. You testified</p>	<p style="text-align: center;">Page 273</p> <p>1 A. Yes, I would have to speculate on that, 2 even on the, the opinion about the TVT causing a 3 pudendal nerve injury, the corona study, they actually 4 write a sentence saying we speculate that this is 5 what's causing it.</p> <p>6 Q. I'm not sure what that's responding to so 7 I'll move to strike. And if Dr. Zimmern's surgery in 8 fact caused a pudendal nerve injury, it will be the 9 first time in the history of your practice as a doc 10 you've ever seen it, correct?</p> <p>11 A. Yes. That would be the first time that I 12 see it described beyond what has, for an explanting, 13 explanting surgery.</p> <p>14 Q. Okay. This would be the first time in an 15 explant surgery that you've ever seen, heard, reported 16 anything, where a pudendal nerve was caused by that, is 17 Dr. Zimmern's surgery on Jennifer?</p> <p>18 A. The first explanting surgery, I'm not 19 aware of any report, even case reports of an explanting 20 surgery for TVT causing a pudendal nerve injury.</p> <p>21 Q. And you've done three in your life, 22 maybe?</p> <p>23 A. Excisions?</p> <p>24 Q. Yes.</p> <p>25 A. Yes, I don't take many slings out.</p>

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<p>1 Q. Do you have any idea how many revision 2 surgeries Dr. Zimmern has done? 3 A. No, I can not count that. 4 (Plaintiff's Exhibit No. 23 was marked 5 for identification.) 6 BY MR. FREESE: 7 Q. Let me show you Exhibit 23, sir. Have 8 you ever seen article this before, sir? 9 A. No, I have not seen it before. 10 Q. This is an article by Doctors Hibner, 11 Castellanos and Desai. Do you see that, they're 12 doctors at Division of Surgery and Pelvic Pain at 13 Creighton University School of Medicine and -- you see 14 this? 15 A. Yes, I do see the article. I have not 16 read the article, though. 17 Q. Let's start on, where it says 18 introduction. It says pudendal neuralgia was first 19 described in 1987 by Amarenco. It is a severely 20 painful and disabling neuropathic condition affecting 21 both men and women. Do you see that? 22 A. Yes. 23 Q. Do you agree with that? 24 A. Well, that's what it says here. 25 Q. It says pudendal neuropathy yields, when</p>	<p>1 as an expert. I think that pudendal nerve injuries, 2 being as rare as they are, not even the best attempt of 3 defining a criteria has been successful. 4 Q. I'll accept that. So you don't consider 5 yourself as an expert on pudendal nerve injury because 6 you don't think anyone exists, correct? 7 MS. GALLAGHER: Object to form. 8 A. Well, I'm an expert on pelvic floor, I'm 9 an expert on female pelvic medicine, and that qualifies 10 me to give an opinion about the pudendal nerve. 11 BY MR. FREESE: 12 Q. Well, we'll see about that. Let's look 13 on the symptoms page. It's the third page, sir. 14 A. Yes. 15 Q. You see it says patients with pudendal 16 neuralgia are often diagnosed with interstitial 17 cystitis, vulvodynia, dyspareunia, and persistent 18 sexual arousal. Do you see that? 19 A. Yes. 20 Q. Do you agree with that? 21 A. Yes, I would say that that's, I would 22 understand that, yes. 23 Q. Did you ever make any finding that 24 Jennifer was, had any kind of case of interstitial 25 cystitis?</p>
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<p>1 they searched pudendal neuropathy, they got 115 2 publications. It says few of them discuss diagnosis or 3 treatment. Still, this syndrome is often unrecognized 4 by a majority of physicians, including physicians 5 experienced in pelvic pain, such as gynecologists, 6 urologists and neurologists. Do you see that? You 7 agree with that? 8 A. Well, I would need to read the whole 9 article, Mr. Freese. I've never read this article 10 before. But if you wanted me to give you an opinion on 11 it, you could have forwarded it to me before today. 12 Q. Well, I'm just showing it to you now, 13 because you're giving an opinion, you're the expert on 14 behalf of Ethicon for this pudendal nerve injury, are 15 you not? 16 A. I'm an expert for TVTO. The pudendal 17 nerve injury is something that came after recent 18 findings. 19 Q. I understand, but you're the witness 20 designated by the company as the urogynecologist to 21 testify about it, correct? 22 A. Yes. 23 Q. All right. Are you an expert on pudendal 24 nerve injuries or not? 25 A. I don't think that there is such a thing</p>	<p>1 A. No. 2 Q. What about dyspareunia? 3 A. Dyspareunia, it's a complaint that she 4 has had. 5 Q. Okay. And the literature says that is 6 oftentimes what is diagnosed in patients when they 7 actually really have pudendal nerve injury, correct? 8 A. Yes. 9 Q. All right. By the way, Doctor, before 10 you formed your opinions about pudendal nerve injury, 11 did you do a thorough literature review in order to 12 satisfy yourself that you knew enough to give an 13 opinion about pudendal nerve injury? 14 A. No, I rely on the diagnosis of pudendal 15 nerve injury on the exam of Dr. Kelly Scott. 16 Q. So just take her diagnosis of pudendal 17 nerve injury; you didn't do a literature search and 18 attempt to satisfy yourself what all the literature 19 says about pudendal nerve injury and what causes it, 20 correct? 21 A. No, before she made the diagnosis with 22 all the whole extent of the records that I saw, there 23 was no indication of a pudendal nerve injury. 24 Q. That's not what I'm asking you. In 25 formulating your opinions, you haven't even done a</p>

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<p>1 search of the pudendal nerve injury databases and found      2 out what the literature is out there on pudendal nerve      3 injury and what if any connection there is to synthetic      4 mesh, is that fair?</p> <p>5 A. Yes, I did do a PubMed. Once I saw that      6 there was a finding, I went to PubMed and checked for      7 papers about pudendal nerve injuries.</p> <p>8 Q. And you didn't find Exhibit Number 23,      9 did you?</p> <p>10 A. No, because it has no description of a      11 TVTO.</p> <p>12 Q. So the only thing you searched was      13 pudendal nerve TVTO?</p> <p>14 A. Yes, I wanted to know if that was      15 associated to it. I wanted to know if hysterectomy      16 could be associated to it. I wanted to know if any      17 other procedures done for incontinence could be      18 associated to it.</p> <p>19 Q. How about typing in mesh, synthetic mesh      20 and pudendal nerve injury, did you do that search?</p> <p>21 A. No, that would be an inaccurate search      22 because that does not define meshes for urinary      23 incontinence. That search would be inaccurate.</p> <p>24 Q. Well, that's how I found in this article.      25 I typed in synthetic mesh and pudendal nerve, and this</p>	<p>1 fact that it's described as may, not as causes, does      2 not limit the, that to those causes. To those five      3 distinct mechanisms.</p> <p>4 Q. Do you agree that at least those five      5 distinct mechanisms?</p> <p>6 A. That's one of the five mechanisms of the      7 whole spectrum of the universe.</p> <p>8 Q. Which one of these would Jennifer's      9 pudendal nerve injury caused by Dr. Zimmern fall under?</p> <p>10 A. It's the dissection.</p> <p>11 Q. Which one of these five categories?</p> <p>12 A. Oh, this doesn't list a surgery. I'm      13 going to tell you why they don't list surgery, because      14 this is about myalgia, this is about neuralgia, and      15 there is a difference between neuropathy and there is a      16 difference between neuralgia.</p> <p>17 Q. Well, you know, the article actually      18 addresses that and says they're essentially used      19 interchangeably. So what is the difference between      20 neuropathy and neuralgia?</p> <p>21 A. To be diagnosed as a neuralgia, you have      22 to have it in all the branches, and neuropathy is just      23 in any of the segments. That's why you see in here      24 that it doesn't define for neuropathy or neuralgia in      25 this specific area. I'm going to explain that better</p>
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<p>1 article was the first one that popped up, and you're      2 saying you didn't find it because that would have been      3 wrong to search for synthetic mesh and pudendal nerve      4 injury?</p> <p>5 A. Yes, that's an inaccurate search. You      6 have to look for sling, midurethral slings, TVTO, any      7 other sling. Incontinence procedure.</p> <p>8 Q. All right. And if you look at cause for      9 pudendal neuralgia, do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. It says pudendal neuralgia may arise from      12 five distinct mechanisms. First, there may be a direct      13 injury to the nerve. Second, pelvic floor muscle      14 spasms or pelvic floor tension myalgia may cause      15 compression of the nerve. Third, pelvic floor muscle      16 alone, without pudendal neuropathy, may also mimic      17 pudendal neuralgia symptoms, and fourth, biochemical      18 injury from infection or disease. Finally, there may      19 be compression of the spinal cord nerve roots. Do you      20 see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you agree first of all that those are      23 the five distinct mechanisms that cause pudendal nerve      24 injury?</p> <p>25 A. That's listed as it may arise. So the</p>	<p>1 in a second. These are five possible causes. If      2 you're looking at the cause of irritation on this      3 pudendal nerve, it has to be the dissection. There was      4 no pudendal symptoms before her surgery.</p> <p>5 Q. Move to strike. That's not my question,      6 Doctor. Are you telling me that this article that      7 identifies five distinct mechanisms, none of which      8 applied to Jennifer as a cause of pudendal nerve      9 injury, correct?</p> <p>10 A. There are other factors in here. It      11 could be direct injury by palpation.</p> <p>12 Q. That's what I'm saying. I was giving you      13 the chance. Are you saying that the direct injury by      14 Dr. Zimmern's finger dissection caused the pudendal      15 nerve injury, that's what you're saying, right?</p> <p>16 A. That could cause that, yes.</p> <p>17 Q. Would that be under the category of a      18 direct injury to the nerve?</p> <p>19 A. Yes, could be a direct injury to a nerve.</p> <p>20 Q. Okay. And if you look down, it says,      21 quote, "Permanent compression of the nerve is caused by      22 adhesions or foreign bodies such as mesh or suture      23 entrapping the nerve." Do you see that?</p> <p>24 A. Yes, but we know that there's no mesh      25 entrapping this nerve.</p>

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<p>1       Q. Hold on a second. How do you know that?</p> <p>2       A. Because there was no report on her</p> <p>3       neurography report.</p> <p>4       Q. Have you looked at Dr. Eickoff's report?</p> <p>5       A. I saw his report, yes, I saw his slides.</p> <p>6       Q. Did you see any nerve entrapment reported</p> <p>7       in his report?</p> <p>8       A. No.</p> <p>9       Q. I'm not asking you if you saw it, do you</p> <p>10      know whether Dr. Eickoff reported nerve entrapment?</p> <p>11      A. No, he did not report nerve entrapment.</p> <p>12      He report a nerve growing around the, around the scar.</p> <p>13      Q. Permanent compression of the nerve is</p> <p>14      caused by adhesions or foreign bodies such as mesh or</p> <p>15      suture entrapping the nerve. Do you see that?</p> <p>16      A. Yes.</p> <p>17      Q. That cites an article, Fisher, Lotze,</p> <p>18      Nerve Injury Locations During Retropubic Sling</p> <p>19      Procedures, International Urogynecologic Journal,</p> <p>20      Pelvic Floor Dysfunction. Did you find that article?</p> <p>21      A. Yes.</p> <p>22      Q. You have seen that article before?</p> <p>23      A. I see that.</p> <p>24      Q. Okay. If you look down at causes of</p> <p>25      pudendal neuralgia -- first of all, do you dispute that</p>	<p>1       article, and i haven't read it, I haven't confirmed it.</p> <p>2       Q. You might have seen it in another</p> <p>3       article.</p> <p>4       A. No, I don't see it.</p> <p>5       Q. So, this is the first time that you've</p> <p>6       seen authors published saying that the number one cause</p> <p>7       of pudendal neuralgia is pelvic surgery, especially</p> <p>8       with the use of mesh?</p> <p>9       A. Yes, I don't see, I don't, I haven't read</p> <p>10      this article, I cannot give you an opinion on this</p> <p>11      article.</p> <p>12      Q. So, I'm showing you an article on</p> <p>13      pudendal neuralgia. It's an opinion you hold in this</p> <p>14      case and you can't comment on this article because</p> <p>15      you've never seen it, correct?</p> <p>16      A. It's an article that I have not read.</p> <p>17      Q. I know, I'm saying you can't even comment</p> <p>18      on it because you never read it before, correct?</p> <p>19      A. I cannot comment on this article.</p> <p>20      Q. Now, are you familiar with a Nantes</p> <p>21      criteria?</p> <p>22      A. Yes.</p> <p>23      Q. Okay, and the inclusion criteria for</p> <p>24      pudendal nerves, if you turn to the next page you'll</p> <p>25      see that. You see the inclusion criteria?</p>
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<p>1       Jennifer has pudendal neuralgia?</p> <p>2       A. No, she described the pain that was</p> <p>3       alleviated by a block.</p> <p>4       Q. Okay. So you agree Jennifer does have</p> <p>5       pudendal neuralgia?</p> <p>6       A. I agree with Dr. Kelly Scott's diagnosis.</p> <p>7       Q. That she has pudendal neuralgia?</p> <p>8       A. Yes.</p> <p>9       Q. Okay. According to this article, see</p> <p>10      where it says table, causes of pudendal nerve</p> <p>11      neuralgia? What is the very first thing that the</p> <p>12      authors identify as the cause of pudendal neuralgia?</p> <p>13      A. They list pelvic surgery, especially with</p> <p>14      the use of mesh.</p> <p>15      Q. And you didn't know that before I just</p> <p>16      showed you that article, did you?</p> <p>17      A. No, because I had not read the article.</p> <p>18      I have not read this article.</p> <p>19      Q. Did you have to read this article to know</p> <p>20      that the number one cause of pudendal neuralgia is</p> <p>21      pelvis surgery, especially with the use of mesh?</p> <p>22      A. How could I give you an opinion about</p> <p>23      this article? I have not read the article, I have not</p> <p>24      confirmed the bibliographies on the back. You're</p> <p>25      essentially showing me this, which is supposed to be an</p>	<p>1       A. Yeah, that's the Nantes test criteria.</p> <p>2       Q. And you're familiar with that?</p> <p>3       A. Yes, I am aware of how it was done.</p> <p>4       Q. All right. Pain in the area innervated by</p> <p>5       the pudendal nerve. Jennifer has that, correct? She</p> <p>6       has pain in the area innervated by the pudendal nerve.</p> <p>7       a. In one of the segments.</p> <p>8       Q. So, she has that. Pain more severe with</p> <p>9       sitting. She has that, does she not?</p> <p>10      A. Yeah, actually I have searched on that</p> <p>11      pain when she was sitting, and there is no description</p> <p>12      before her surgery that she required to sit on any type</p> <p>13      of cushion. The only time that she had described that</p> <p>14      she had to sit on a cushion was afterwards.</p> <p>15      Q. Was after the Zimmern?</p> <p>16      A. After her explanatory surgery.</p> <p>17      Q. You agree she meets all the Nantes</p> <p>18      criteria?</p> <p>19      A. No, I do not agree because there's</p> <p>20      testimony on Dr. Kelly Scott's deposition that pain</p> <p>21      that does not awaken patients from sleep is not a</p> <p>22      criteria that she has.</p> <p>23      Q. So she's got four of the five, which in</p> <p>24      Dr. Scott's opinion was enough to include her and</p> <p>25      diagnose her with pudendal nerve injury, correct?</p>

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<p>1        A. Yes, and this is the situation that we      2 find with a Nantes criteria. This is a criteria that      3 is not based on evidence, it was put together on a      4 weekend in September of 2006, two days. That's what      5 they took to come up with the criteria.</p> <p>6        Q. So you're criticizing the Nantes      7 criteria?</p> <p>8        A. Yes, I am.</p> <p>9        Q. Will I find that anywhere in your report,      10 that you criticize the inclusion criteria?</p> <p>11      A. When I look at the --</p> <p>12      Q. Just answer my question, Doctor. Will I      13 find in your report anywhere your criticism of the      14 Nantes criteria?</p> <p>15      A. No, you will not find it in the report.</p> <p>16      Q. Now, would you look at the associated      17 signs for pudendal neuralgia?</p> <p>18      A. Yes.</p> <p>19      Q. Referred sciatic pain, do you see that?</p> <p>20      A. Yes.</p> <p>21      Q. Tell me how referred sciatic pain would      22 be described by a patient.</p> <p>23      A. The patients describe pain as the sciatic      24 nerve.</p> <p>25      Q. I know, but if I was describing sciatic</p>	<p>1        doesn't she?</p> <p>2        A. She has reported urinary frequency, just      3 that it has not been with a full bladder like you just      4 represented.</p> <p>5        Q. Dyspareunia or pain after intercourse.      6 Do you see that?</p> <p>7        A. Yes.</p> <p>8        Q. She reported that since way before Dr.      9 Zimmern did his surgery, did she not?</p> <p>10      A. She reported dyspareunia actually before      11 Dr. Reyes' surgery.</p> <p>12      Q. Doctor, listen to my question. She      13 reported dyspareunia and described it as pain after      14 intercourse, did she not?</p> <p>15      A. I don't recall the pain after      16 intercourse. I do recall the dyspareunia.</p> <p>17      Q. Will you at least defer to her in her      18 deposition if she said that she described part of the      19 dyspareunia as pain after intercourse?</p> <p>20      A. I would defer to her description.</p> <p>21      Q. And you wouldn't dispute that, correct?</p> <p>22      A. I would not dispute her description.</p> <p>23      Q. And you agree that me that's an      24 associated sign of pudendal nerve injury, is it not,      25 that is dyspareunia or pain after intercourse?</p>
<p style="text-align: center;">Page 287</p> <p>1        pain, how would I describe it?</p> <p>2        A. It's a pain that comes through the back      3 and goes down.</p> <p>4        Q. Down the leg?</p> <p>5        A. Down the leg, yeah.</p> <p>6        Q. Just the way Jennifer reported it,      7 correct?</p> <p>8        MS. GALLAGHER: Object to form.</p> <p>9        A. No, she reported the pain to be in the      10 front, to the medial aspect down the leg.</p> <p>11 BY MR. FREESE:</p> <p>12      Q. And you think she's not reported what,      13 from a layman's standpoint what would be described as      14 sciatic pain?</p> <p>15      A. Not as typical sciatic pain, no.</p> <p>16      Q. Okay. Urinary frequency with full      17 bladder. Does she have that?</p> <p>18      A. There's no urodynamics to confirm that.</p> <p>19      Q. Well, does she report urinary frequency      20 with a full bladder, yes or no?</p> <p>21      A. She feels she does not empty completely.</p> <p>22      Q. I'm talking about frequency.</p> <p>23      A. I don't recall her frequency is with a      24 full bladder, there is no description of that.</p> <p>25      Q. She reports frequency all the time,</p>	<p style="text-align: center;">Page 289</p> <p>1        A. I agree that this is disclosed in this      2 article here.</p> <p>3        Q. And you will agree with me that she      4 reported it in her deposition and reported it in      5 medical records prior to Dr. Zimmern's surgery,      6 correct?</p> <p>7        A. She reported dyspareunia before her      8 explant surgery, yes.</p> <p>9        Q. And reported dyspareunia after sex before      10 Dr. Zimmern's surgery?</p> <p>11      A. I just answered that, I don't recall      12 that.</p> <p>13      Q. If she said it, then you accept it?</p> <p>14      A. I would have to defer to her. I just      15 said I would defer to her.</p> <p>16      Q. Thank you. Now, Doctor, am I correct      17 that your reference point in determining the cause of      18 the pelvic pain is always that it cannot be caused by      19 the mesh because it's your opinion that it's always the      20 mesh itself cannot cause pain?</p> <p>21      MS. GALLAGHER: Object to form.</p> <p>22      A. Yes, the mesh itself don't cause, don't      23 cause pain.</p> <p>24 BY MR. FREESE:</p> <p>25      Q. But that's an opinion you hold across the</p>

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<p>1 board no matter what woman you're looking at, it is the      2 opinion of Jaime Sepulveda that mesh cannot cause pain,      3 you go into your differential diagnosis holding that      4 opinion, correct?</p> <p>5 MS. GALLAGHER: Object to form.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Just answer that question. Do you go      8 into your differential diagnosis holding that opinion?</p> <p>9 MS. GALLAGHER: Object to form.</p> <p>10 A. Well, I go into the differential      11 diagnosis understanding that there is no evidence that      12 just a single implantation of a mesh implant by itself,      13 with no other procedures, would cause pain. And that's      14 going to be, and I do understand that it's going to be      15 a very difficult test to do and a difficult thing to      16 obtain, it will require inference, so I do understand      17 the limitations of the science in that.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. Okay, and just so we're clear, if you're      20 going to do a differential diagnosis, mesh causing the      21 pain or mesh causing dyspareunia or mesh causing groin      22 pain or mesh causing pudendal nerve injury, you're      23 always going to find something other than mesh because      24 you don't believe mesh can ever cause any of that      25 anyway?</p>	<p>1 that on the patients that are referred to me.      2 Q. One hundred percent of the time, you      3 found something other than mesh causing an adverse      4 complication?</p> <p>5 MS. GALLAGHER: Object to form.</p> <p>6 A. So far, is what I have seen.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. And the reason you hold that opinion, Dr.      9 Sepulveda, is because you don't believe that there's      10 any science supporting the concept that mesh by itself      11 can cause pain. Fair?</p> <p>12 A. The reason why I hold, I hold this      13 opinion is because when I look at the whole clinical      14 picture, when I look at all the data that has been      15 published and when I look at what has been published      16 about mesh by itself causing pain, I cannot conclude,      17 based on all the evidence that I have, that mesh by      18 itself is what causes pain.</p> <p>19 Q. Because you believe there's no science      20 that says mesh by itself causes pain, correct?</p> <p>21 A. Right, mesh by itself does not cause      22 pain.</p> <p>23 MR. FREESE: Let's take a break.      24 (Break was taken from 4:05 p.m. to 4:20      25 p.m.)</p>
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<p>1 MS. GALLAGHER: Object to form.</p> <p>2 A. I would look at the whole patient. In      3 other words, I would not just look at mesh as the cause      4 because it's not as simple as just mesh causing pain.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. I understand that, but when you do a      7 differential diagnosis, you've already concluded that      8 it doesn't cause it, so therefore it cannot be the      9 cause of any complication that any woman suffers,      10 correct?</p> <p>11 MS. GALLAGHER: Object to the form.</p> <p>12 A. If I can exclude all the other causes, I      13 can rule out all the other causes, and the only one I'm      14 left with is mesh, I will conclude that.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. Okay, but you've always concluded it's      17 never mesh because you hold the opinion it's always      18 something else other than the mesh causing the      19 complications?</p> <p>20 MS. GALLAGHER: Object to form.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. Fair?</p> <p>23 A. I have found, I have found, I have found      24 in almost every instance other causes of pain, and I      25 find that on the cases that I review, and I also found</p>	<p>1 MR. FREESE: We marked the thumb drive as      2 Exhibit 15. The password for Exhibit 15 is      3 capital S, Sepulveda 1234 exclamation point.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. Dr. Sepulveda, back to your report. It      6 is your opinion that Dr. Zimmern's surgery caused the      7 pudendal nerve injury because he got into the      8 ischiorectal fossa, that's what you were talking about,      9 that's i-s-c-h-i-o-r-e-c-t-a-l, fossa, f-o-s-s-a,      10 correct?</p> <p>11 A. Yes, the ischiorectal fossa is also known      12 as ischioanal space.</p> <p>13 Q. And it's your opinion that Dr. Zimmern      14 got his finger in the anal rectal space, or the anal      15 fossa space?</p> <p>16 A. Yes, on the dissection, if you have a      17 patient that has very little fibers on the levators,      18 you can easily get to that space.</p> <p>19 Q. And it doesn't matter whether or not      20 there was a levator muscle avulsion or not, he still      21 could have gotten to the ischiorectal fossa with his      22 finger, whether or not there was a muscle avulsion?</p> <p>23 A. I believe that the muscle avulsion in      24 that area just made it much more accessible.</p> <p>25 Q. I understand, but could he have gotten to</p>

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<p>1 that space with his finger if it wasn't for a muscle 2 avulsion?</p> <p>3 A. Yes, I think it would be less likely for 4 him to get there. You can always get there as, without 5 an avulsion. When you dissect in cadavers and you get 6 to that space from the obturator space, it doesn't 7 always have a levator avulsion.</p> <p>8 Q. So it doesn't matter whether or not 9 there's an avulsion here in Jennifer or not, it's still 10 Dr. Zimmern's finger in the ischiorectal fossa that 11 caused the pudendal nerve injury?</p> <p>12 A. Yes, there was, there was a manipulation 13 of that space where the pudendal nerve sits that caused 14 that injury. To what degree the levator avulsion 15 contributed to it, that's why I can not give you a 16 certainty.</p> <p>17 Q. Okay. And am I correct that you have 18 never seen a pudendal nerve injury caused by the way 19 you're describing this in your career, correct?</p> <p>20 A. No, I have not seen it.</p> <p>21 Q. And you have never seen any literature 22 describing a pudendal nerve injury being caused by a 23 surgeon's finger going into the ischiorectal fossa?</p> <p>24 A. No, I have not seen it described with an 25 explantation surgery.</p>	<p>1 BY MR. FREESE: 2 Q. I understand, but if they decide it, they 3 will be deciding something that you have never seen, 4 that's never been reported, there's no study, there's 5 no literature anywhere saying that a pudendal nerve 6 injury can be caused this way, and they would have to 7 accept for the first time in mankind known your opinion 8 that the pudendal nerve injury was caused by Dr. 9 Zimmern's finger. Correct?</p> <p>10 MR. WALKER: Objection.</p> <p>11 A. Either by his finger, or in the thousands 12 of cases of TVTO, or in the few that has been resected, 13 there has not been a reported pudendal nerve injury.</p> <p>14 BY MR. FREESE: 15 Q. By a surgeon's finger? 16 A. By a surgeon's finger or an 17 instrumentation during an explantation.</p> <p>18 Q. You're saying finger, there's been no 19 pudendal nerve injury ever caused by anything a doctor 20 was trying to do in explanting a mesh?</p> <p>21 A. Yes, but I can, I can tell you that the 22 only person that knows what instrument was, was used 23 ultimately would be Dr. Zimmern.</p> <p>24 Q. That's what I asked you. You said your 25 best opinion is it was his finger.</p>
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<p>1 Q. And it's never been described at a 2 conference or a society?</p> <p>3 A. No.</p> <p>4 Q. There's been no case studies?</p> <p>5 A. No reports of, of this, of an 6 explantation causing pudendal nerve injury.</p> <p>7 Q. So, if a jury is to accept the 8 reliability that Dr. Zimmern's finger dissection caused 9 the pudendal nerve injury, it would be the first time 10 in medical history, in this world, that you know of, of 11 that ever happening, correct?</p> <p>12 MR. WALKER: Object to form.</p> <p>13 A. It has not been reported, to my 14 knowledge.</p> <p>15 BY MR. FREESE: 16 Q. Listen to my question. It will be the 17 first time in the medical history of this world that a 18 pudendal nerve injury was injured by a surgeon's finger 19 getting into the ischiorectal space during a mesh 20 removal, correct?</p> <p>21 MR. WALKER: Objection.</p> <p>22 A. Yeah, that would be, that would be, there 23 have been no reports, but whatever the jury decides 24 obviously isn't up to me you or me, it's up to the 25 jury.</p>	<p>1 A. That is my best opinion.</p> <p>2 Q. Does it matter to your opinion whether or 3 not it was a finger or an instrument?</p> <p>4 A. No, no.</p> <p>5 Q. If it was a finger or a blunt instrument, 6 scissors, scalpel, it was the dissection into the 7 ischio fat fossa?</p> <p>8 A. Yes.</p> <p>9 Q. That caused the pudendal nerve injury?</p> <p>10 A. Yes. That irritated the pudendal nerve.</p> <p>11 Q. And if Dr. Zimmern didn't get into the 12 ischio fossa during his surgery, then your opinion 13 wouldn't be reliable, would it? If it's concluded by 14 the jury that neither his finger nor his blunt 15 instrument or anything entered into that area, would 16 you withdraw that opinion?</p> <p>17 A. If the ischio -- and that's a very 18 interesting question. If the ischioanal fossa was not 19 entered, or the ischiorectal fossa, if it was not 20 entered, then we'll have to look for other reasons why 21 there was a pudendal nerve injury.</p> <p>22 Q. Sitting here today, do you have any, is 23 there an option B or are we only on option A?</p> <p>24 A. No, I think, I think that there's, 25 whenever you have something that happened after the</p>

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<p>1 surgery, always leads you to believe that it has do      2 with the surgery. So, if it was, if it was something      3 that caused this pudendal nerve injury before surgery,      4 it should have been diagnosed before surgery.      5 Now, there is only one, one limitation to      6 this, is that Mrs. Ramirez did not get to see Dr. Kelly      7 Scott before her surgery.      8 Q. I mean, it is what it is. But, what I'm      9 saying is, do you have -- what's the next likely cause      10 if it wasn't Dr. Zimmern?      11 A. It was, it was the surgery that was done      12 for the explantation. That's the most likely cause.      13 Q. I know, I said -- but you said if it      14 turns out that he didn't get into that ischio fossa      15 space, then you would have to look for the next option.      16 A. Which is something that happened before,      17 but I have nothing to support an opinion on that.      18 Q. That's what I'm saying. It's either he      19 got into the ischio fossa space and caused a pudendal      20 nerve injury; if he didn't get into that space, then      21 you don't have an opinion that his surgery caused the      22 pudendal nerve injury, correct?      23 A. Right, that's what the, that's what the      24 pudendal nerve is.      25 Q. And you would have no opinion to what</p>	<p>1 it's the tiny chart.      2 MR. FREESE: Yeah, you can go ahead and      3 we'll substitute it as Exhibit 7.      4 BY MR. FREESE:      5 Q. Am I correct, Dr. Sepulveda, that in      6 certain years that you have been paid in excess of      7 \$280,000 by Ethicon to provide consulting services?      8 A. I don't believe that that's, that that's      9 accurate. It may have been now on the legal      10 consultation, but not, not before.      11 Q. Well, how about in 2010, six years ago,      12 you're saying you've never been paid more than \$280,000      13 in that year by Ethicon?      14 A. No, they may have budgeted for that, but      15 I don't believe that they paid me that amount of money.      16 (Plaintiff's Exhibit No. 24 was marked      17 for identification.)      18 BY MR. FREESE:      19 Q. Okay. Let me show you what I've marked      20 as Exhibit 24 to your deposition. Have you seen this      21 document before?      22 A. Yes.      23 Q. Okay. It says from Ron Horton and to a      24 number of people, subject, KOL usage. That's you, KOL,      25 that's Key Opinion Leader usage, correct?</p>
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<p>1 caused it then after that?      2 A. No, I'm not aware of anything else      3 causing it is afterwards.      4 Q. And so, if, if it, if it's proven or if      5 you're satisfied that he didn't get into that space, by      6 later testimony or later evidence, you don't have      7 another theory or another opinion about what caused the      8 pudendal nerve injury, correct?      9 A. No, I don't have anything else that could      10 explain it, sir.      11 Q. Like the mesh, for example, that would      12 never be your opinion?      13 A. Well, it's, the mesh is distant from the      14 ischioanal fossa.      15 Q. Now, Doctor, am I correct that, in the      16 time that you have consulted for Ethicon, that you have      17 been paid in excess of a million dollars by them?      18 A. It's -- you mean over the last ten years?      19 Q. Yes, sir.      20 A. It may have amount to that, yes.      21 MR. WALKER: Before you go further, I do      22 have a new version that looks more readable.      23 Do you want me to email that to Tim?      24 MR. FREESE: Sure. It's Exhibit 7?      25 MR. WALKER: Yeah, well, it's the first,</p>	<p>1 A. Right.      2 Q. And if you'll look down, this is dated      3 November 19th, 2010, correct?      4 A. This is November 19th, 2010.      5 Q. If you'll scroll down, you'll see      6 Sepulveda total \$288,400. Correct?      7 A. Sepulveda, 288, yes.      8 Q. And this is not a, like a budgeted      9 contract amount. This is an email saying that, it's      10 listing the highly used KOLs and the total they were      11 paid this year. Do you see that in the first very      12 sentence?      13 A. Yes, that's a, that says the contract      14 amount.      15 Q. No, it doesn't. Sir, it says all, please      16 see the below list of highly used KOLs, and the total      17 pay they have received this year. Did I state that      18 accurately?      19 A. Yes, but it says contract amount in the      20 column on top.      21 Q. Sir, I'm not asking you to look at the      22 column. I'm asking you to look at the sentence. It      23 says the total pay they have received this year. That      24 is an existing fact, isn't it?      25 A. No, that's what he says. I don't know if</p>

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<p>1 it's a fact.</p> <p>2 Q. I understand. You don't have your 1099s 3 with you, correct?</p> <p>4 A. No, I don't.</p> <p>5 Q. You've objected to producing those to us, 6 haven't you?</p> <p>7 A. Yes.</p> <p>8 Q. They would show what you've been paid, 9 correct?</p> <p>10 A. No, they have other things on the 1099s.</p> <p>11 Q. We would know from your 1099s what 12 Johnson &amp; Johnson had paid you, correct?</p> <p>13 A. No, there are other, other incomes that I 14 have.</p> <p>15 Q. You're not listening to me, sir. I would 16 know from your 1099s -- Johnson &amp; Johnson sends you a 17 1099, correct?</p> <p>18 A. They do send a 1099.</p> <p>19 Q. And if I had your Johnson &amp; Johnson 20 1099s, I would know what they paid you in each year.</p> <p>21 A. I don't keep those, I just keep the tax 22 returns.</p> <p>23 Q. I'm not quibbling with you, Dr. 24 Sepulveda. I'm just saying if I had them I would know 25 exactly how much you were paid according to them,</p>	<p>1 have besides Johnson &amp; Johnson in 2010?</p> <p>2 A. Well, I'm a partner at a surgery center, 3 equal partner. I'm also the chairman of the board of 4 that surgery center. I am a part owner of the 5 diagnostic center. I am a shareholder in a management 6 company with over 300 physicians. I am also a full 7 partner in Vital M.D., which is the largest group of 8 gynecologists in the country. Yeah, that's essentially 9 what my income -- and my, obviously my medical-surgical 10 practice where I, I work very hard.</p> <p>11 Q. Doctor, has Johnson &amp; Johnson ever made 12 up more than 50 percent of your income in any year?</p> <p>13 A. More than 50 percent?</p> <p>14 Q. Yes, sir.</p> <p>15 A. No.</p> <p>16 Q. You got divorced in 2012, did you not?</p> <p>17 A. Yes, I did.</p> <p>18 Q. Do you remember signing an affidavit in 19 your divorce saying that your income was \$55,000 a 20 month in 2012?</p> <p>21 A. I don't recall that about my divorce.</p> <p>22 Q. Well, I can have it pulled for you, but 23 I'll represent to you that you signed an affidavit in 24 2012 saying your income was \$55,000 a month. Can I 25 rely on your sworn affidavit?</p>
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<p>1 correct?</p> <p>2 A. No, I don't think you would know that.</p> <p>3 Q. Dr. Sepulveda, I know you may not agree 4 with this, but according to them, in November of 2010, 5 you had been paid \$288,000, correct?</p> <p>6 A. Yes, that's what it says.</p> <p>7 Q. You don't agree that their records are 8 accurate, correct?</p> <p>9 A. I don't recall that number. It could be 10 that number, by the way, it could be that number. I 11 just cannot give you one way or the other if it was 12 that number.</p> <p>13 Q. Well, they say, and this is the only 14 record I've got for that year, and it says you were 15 paid \$288,000. Correct?</p> <p>16 A. Yes, that's what, the contract amount 17 that it shows in here.</p> <p>18 Q. What percentage of your entire income was 19 it that year?</p> <p>20 A. Probably 10, 20 percent, no more than, 21 probably no more than 15.</p> <p>22 Q. So, 288,000 was no more than 15 percent 23 of your income in 2010?</p> <p>24 A. Yes.</p> <p>25 Q. And what other sources of income did you</p>	<p>1 A. On the, on my, for my divorce?</p> <p>2 Q. Yes, sir.</p> <p>3 A. Well, they calculated that.</p> <p>4 Q. No, you signed an affidavit warranting 5 and representing that your income in 2012 was \$55,000 a 6 month. Is that a true statement?</p> <p>7 A. If I signed it, it must be a true 8 statement.</p> <p>9 Q. And if you were being paid \$288,000 in a 10 year, that's almost, that's almost \$25,000 a month, 11 it's more than \$25,000 a month, is it not?</p> <p>12 A. No, I don't, I don't, I don't believe 13 that that's 55,000, but I also took bonuses. The 14 income that I think you have is what I get from the 15 office from my medical practice.</p> <p>16 Q. No, sir, you represented the entirety of 17 your income was \$55,000 a month in your asset 18 affidavit.</p> <p>19 A. Okay.</p> <p>20 Q. Do you stand by your affidavit that was 21 filed in Dade County court?</p> <p>22 A. Right. Yes.</p> <p>23 Q. Okay, and it said \$55,000 a month was 24 your income in 2012.</p> <p>25 A. I don't know, I haven't seen that. Do</p>

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<p>1 you have it?</p> <p>2 Q. I do. I don't have a copy of it right</p> <p>3 now. I'll supply it to your lawyer, though.</p> <p>4 MR. WALKER: We would make that request.</p> <p>5 MR. FREESE: Sure. I'll be happy to do</p> <p>6 that.</p> <p>7 (Plaintiff's Exhibit No. 25 was marked</p> <p>8 for identification.)</p> <p>9 BY MR. FREESE:</p> <p>10 Q. Let me show you what I've marked as</p> <p>11 Exhibit 25. Did you, in 2009, did you make \$388,000</p> <p>12 from Johnson &amp; Johnson?</p> <p>13 A. I don't know exactly what I made at that</p> <p>14 time.</p> <p>15 Q. All right. Because we don't have the</p> <p>16 records, correct?</p> <p>17 A. No, we don't have that.</p> <p>18 Q. Look at Exhibit 25, and if you would turn</p> <p>19 to page, it's the second from the back, sir. You see</p> <p>20 where it says Sepulveda total, and goes to the left,</p> <p>21 \$388,000?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. So, in 2009, Johnson &amp; Johnson is</p> <p>24 reporting payments to you of \$388,000, correct?</p> <p>25 A. That's the number that is written there,</p>	<p>1 A. I may have been paid that, but I didn't</p> <p>2 look into it.</p> <p>3 (Plaintiff's Exhibit No. 26 was marked</p> <p>4 for identification.)</p> <p>5 BY MR. FREESE:</p> <p>6 Q. Okay. Now, let's look at Exhibit 26 to</p> <p>7 your deposition. Do you recall that, and you may not</p> <p>8 even know this, that you were one of the highest paid</p> <p>9 KOLs in 2009 and therefore, Johnson &amp; Johnson put</p> <p>10 together some, some rules that your pay had to be</p> <p>11 approved by the top executives of the company, did you</p> <p>12 know that?</p> <p>13 A. No.</p> <p>14 Q. Do you know who Gary Pruden is?</p> <p>15 A. No, I never, I don't recall ever meeting</p> <p>16 or knowing.</p> <p>17 Q. Did you know he was, if not the, one of</p> <p>18 the top executives in Ethicon?</p> <p>19 A. No, I didn't know that.</p> <p>20 Q. All right, if you turn to the second</p> <p>21 page, you see where, December 22nd, 2009, it says, that</p> <p>22 your, Dr. Sepulveda's contract was submitted for</p> <p>23 \$286,650 for the period of January 25th, 2010, through</p> <p>24 January 31st, 2011, which Gary verbally approved, do</p> <p>25 you see that?</p>
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<p>1 yes.</p> <p>2 Q. And you have no reason to dispute that</p> <p>3 number sitting here today, do you?</p> <p>4 A. There's -- let me see this report before</p> <p>5 I, I answer your question. So that's a contract</p> <p>6 amount. It is under the column of contract amount.</p> <p>7 Q. Well, does the column say contract</p> <p>8 amount?</p> <p>9 MR. WALKER: Yeah, it does.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. All right, and how much were you paid in</p> <p>12 2009 of the \$388,000 contract amount?</p> <p>13 A. I don't know.</p> <p>14 Q. It says Arba payment. Do you know what</p> <p>15 Arba payment means?</p> <p>16 A. No, I don't know that.</p> <p>17 Q. You're not disputing that if you get a</p> <p>18 contract amount of 388,000, you were paid the full</p> <p>19 amount in 2009?</p> <p>20 A. I may have been paid, I worked really</p> <p>21 hard through all that year.</p> <p>22 Q. I'm certain you did, sir. I'm not</p> <p>23 disputing that. You're not disputing that you may have</p> <p>24 been paid \$388,000, the full contract amount, in 2009,</p> <p>25 correct?</p>	<p>1 A. I see that.</p> <p>2 Q. And you don't dispute that you were given</p> <p>3 a contract for \$286,000 for calendar year 2010,</p> <p>4 correct?</p> <p>5 A. I have no reason, no basis to dispute one</p> <p>6 way or the other.</p> <p>7 Q. Do you think over 10 years you may be</p> <p>8 pushing \$2 million from them?</p> <p>9 A. No, I don't think so.</p> <p>10 Q. I showed --</p> <p>11 A. But I'm sure that you're, somehow you're</p> <p>12 going to find a way to calculate the whole thing, but I</p> <p>13 don't recall making that. All I know is that I work</p> <p>14 really hard, I do well on my practice, and I put every</p> <p>15 effort in everything I do, a hundred percent.</p> <p>16 Q. I'm not suggesting you don't, Doctor, but</p> <p>17 I've shown you three documents in just three years that</p> <p>18 are pushing at a million dollars. So over 10 years you</p> <p>19 think you might be pushing \$2 million?</p> <p>20 A. I cannot testify one way or the other</p> <p>21 because I haven't looked into it.</p> <p>22 Q. How about \$10 million, do you think you</p> <p>23 might have been paid \$10 million in 10 years?</p> <p>24 A. No, I think I would have been retired if</p> <p>25 that was the case.</p>

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<p>1 Q. So you know it's not \$10 million, right?      2 A. No, it's not.      3 Q. How about \$5 million?      4 A. I don't think so, either.      5 Q. You're between 1 million and 5 million?      6 A. I don't, I don't think it could get close      7 to 2 million. I, I may have made a million, which is      8 what you say.      9 Q. Well, I've just shown you three years and      10 it's a million, correct?      11 A. Yeah, those are very active years, very      12 busy years.      13 Q. So, but it could be as much as 2 million      14 but you don't think it's over 2 million?      15 A. Right, I don't think so.      16 MR. FREESE: I think I'm going to stop,      17 Tim's got some questions, and I think we'll be      18 done with Dr. Sepulveda.</p> <p style="text-align: center;">CROSS EXAMINATION</p> <p>19 BY MR. GOSS:</p> <p>21 Q. Dr. Sepulveda, we've met several times      22 before, but for the record I'm Tim Goss, and I also      23 represent the plaintiff. I just have a few questions      24 for you regarding the IFU.      25 A. Yes, sir.</p>	<p>1 Q. And does a doctor expect that the IFU      2 will include those adverse risks that are reasonably      3 associated with the product?      4 A. Yes, just the way you said it.      5 Q. Do you believe that if a company has two      6 different products, that both do the same thing and      7 have the same efficacy, but one has a greater risk than      8 the other, that the company should only offer doctors      9 that product with the less risk?      10 A. I think that, for each product, each      11 doctor needs to be trained and each should be made      12 aware of the details of the product.      13 Q. Okay, and I really don't want to hide the      14 ball on this. I think you know where I'm going on      15 this. I understand that you believe, it's your opinion      16 that laser-cut mesh and mechanically-cut mesh have the      17 same efficacy and have the same risks?      18 A. Yes.      19 Q. Okay. I want you to assume      20 hypothetically for me that they have the same efficacy,      21 but one has a greater risk profile than the other.      22 Should the company only offer the one with the less      23 risk profile?      24 A. I think that the risk profile needs to be      25 defined. The surgeons using it need to research and</p>
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<p>1 Q. First of all, do you intend to offer any      2 opinions regarding the IFU from the TVTO?      3 A. My only opinion is my, my own use, and      4 how it was used on the cadaver. That's the extent of      5 my opinions on the IFU.      6 Q. So you don't intend to offer any opinions      7 regarding whether the IFU adequately set forth the      8 risks relating to the TVTO?      9 A. I have the reasons I explained there and      10 we already went through that today. So I don't have      11 any addition to it.      12 Q. You're not a regulatory expert?      13 A. No, I don't make a living or bill for      14 regulatory advice.      15 Q. And I might be able to short circuit      16 this. As I understand it, you may have some opinions      17 as to what doctors look for in an IFU, but you don't      18 have, you're not going to offer any opinions as to what      19 the FDA or any regulatory outfit or what standards in      20 the industry side are for what goes into an IFU?      21 A. I agree with that.      22 Q. Okay. Well, that's going to make this      23 quick. Do you, from the doctor's perspective, does a      24 doctor expect that the IFU will be fair and balanced?      25 A. Yes.</p>	<p>1 then give, tell them this is what we have for, this is      2 a set of our problems or advantages that we have with      3 each one. Obviously we want to use whatever is more      4 advantageous, in our hands, more for our patients.      5 Q. But if science reflects, the medical      6 sciences reflect that the risks for one is greater than      7 the other, shouldn't the company only offer the product      8 that has the better risk profile?      9 A. There's, if it's well defined with      10 medical science that there's one advantage of one over      11 the other, I think the company will have to decide      12 which one they're going to offer, because I don't see      13 any surgeon using any, any product that have a higher      14 risk profile except in those situations in which those      15 surgeons say this doesn't apply to me and this will      16 work better in my hands.      17 Q. If the company internally believed that      18 the risk was greater for one than the other, wouldn't a      19 reasonable manufacturer decide to only offer the      20 product with less risk?      21 MR. WALKER: Object to form.      22 A. I believe that they may as well decide      23 that, yes.      24 BY MR. GOSS:      25 Q. And as a doctor, you would hope that they</p>

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<p>1 would decide that?</p> <p>2       A. I would, if, let's say that in the</p> <p>3 hypothetical scenario that they have a product that</p> <p>4 they decide not to, not to produce, I'll have the</p> <p>5 option of using what they give or go to another company</p> <p>6 that would offer me the product that I need.</p> <p>7       Q. If there was a substantial -- strike</p> <p>8 that.</p> <p>9       If there was a risk that was reasonably</p> <p>10 associated with laser-cut mesh that wasn't associated</p> <p>11 with -- strike that.</p> <p>12       If there was a risk that was reasonably</p> <p>13 associated with mechanically-cut mesh that was not</p> <p>14 associated with laser-cut mesh, would the doctors</p> <p>15 expect the company to put that in the IFU?</p> <p>16       MR. WALKER: Object to the form.</p> <p>17       A. If that's something that's scientifically</p> <p>18 valid, yes.</p> <p>19       BY MR. GOSS:</p> <p>20       Q. And if the company internally believed</p> <p>21 that, would the doctors expect the company to put that</p> <p>22 in the IFU so that the doctors could make their</p> <p>23 decision?</p> <p>24       MR. WALKER: Object to the form.</p> <p>25       A. I would expect scientifically valid</p>	<p>1 whether or not polypropylene mesh degrades?</p> <p>2       A. I may be asked questions about it. I</p> <p>3 think I have testified already last week on, on the</p> <p>4 degradation of polypropylene.</p> <p>5       Q. But you're not a polymer scientist?</p> <p>6       A. No, I'm not a polymer scientist.</p> <p>7       Q. And there are others that are more</p> <p>8 qualified than you to testify about whether or not</p> <p>9 polypropylene degrades?</p> <p>10       A. I think that as a surgeon, there is a</p> <p>11 very limited information that we can give about</p> <p>12 degradation.</p> <p>13       Q. And that would be including yourself?</p> <p>14       A. Yes, we don't have that information one</p> <p>15 way or the other.</p> <p>16       MR. GOSS: Thank you, Doctor.</p> <p>17                   CROSS EXAMINATION</p> <p>18       BY MR. FREESE:</p> <p>19       Q. Dr. Sepulveda, we were talking briefly</p> <p>20 about the particle loss. Remember the discussion we</p> <p>21 had about Jennifer's TVTO sling, and you said Dr. Reyes</p> <p>22 reported he didn't see any particles. Do you remember</p> <p>23 that discussion?</p> <p>24       A. Yes.</p> <p>25       Q. Is the phrase linting the same thing as</p>
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<p>1 information from Ethicon or from any other company.</p> <p>2 BY MR. GOSS:</p> <p>3       Q. And if the company internally believed</p> <p>4 that the risk was greater for one than the other, the</p> <p>5 doctors would at least expect the company to put that</p> <p>6 in the IFU so the doctors could make their own</p> <p>7 decision?</p> <p>8       MR. WALKER: Object to the form.</p> <p>9       A. If they validate that information, yes.</p> <p>10 In other words, I don't want information from them that</p> <p>11 was not validated.</p> <p>12       BY MR. GOSS:</p> <p>13       Q. Well, you want to know what their</p> <p>14 internal opinions are, don't you?</p> <p>15       A. I want to know what's scientifically</p> <p>16 validated.</p> <p>17       Q. You don't care what their internal</p> <p>18 opinions are?</p> <p>19       A. The dynamics that they may have between</p> <p>20 them is less important to me than the actual science</p> <p>21 behind it.</p> <p>22       Q. Well, you would expect them to have</p> <p>23 science to support their opinions?</p> <p>24       A. Yes.</p> <p>25       Q. Do you plan to offer any opinions as to</p>	<p>1 particle loss in your mind?</p> <p>2       A. Which?</p> <p>3       Q. Is the word linting, l-i-n-t-i-n-g, does</p> <p>4 that mean the same thing as particle loss?</p> <p>5       A. No, I don't have -- linting. I've never</p> <p>6 heard that term before to describe any particle loss.</p> <p>7       Q. Have you ever even heard the term linting</p> <p>8 in connection with, with polypropylene mesh?</p> <p>9       A. No.</p> <p>10       Q. And in connection with mechanically-cut</p> <p>11 mesh versus laser-cut mesh?</p> <p>12       A. No, I'm not familiar with that.</p> <p>13       Q. What about the phrase denaturing,</p> <p>14 d-e-n-a-t-u-r-i-n-g?</p> <p>15       A. No, I don't -- denaturing, I know</p> <p>16 chemically from my chemistry what denaturing is, but</p> <p>17 that's not as it relates to a sling.</p> <p>18       Q. To the context of a sling, does the word</p> <p>19 denaturing mean anything to you at all?</p> <p>20       A. No, it doesn't resonate as anything that</p> <p>21 I have read on the slings.</p> <p>22       Q. And what about linting, does that</p> <p>23 resonate in your mind anything as it relates to mesh to</p> <p>24 you?</p> <p>25       A. No.</p>

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<p>Page 318</p> <p>1 Q. And you've never described or had anybody 2 describe to you particle loss as linting or denaturing? 3 A. Yeah, I don't have, I haven't heard any 4 surgeon describing linting or denaturing. 5 Q. Can we agree that particle loss is an 6 unwanted feature of a mesh? You don't want particle 7 loss, correct? 8 A. It's, it's an unwanted feature, but it's 9 something that it may appear with the, with the high 10 pore monofilament that are needed. 11 Q. Do you have an opinion whether or not 12 particle loss is clinically significant? 13 A. No, I don't have an opinion to base on 14 that, how significant particle loss is. 15 Q. Okay. In other words, particle loss 16 could be clinically significant or it might not be, you 17 just don't know because you've never studied it? 18 A. In the surgical scenario, particle loss 19 would be significant only if it reduces the actual 20 length of my sling. 21 Q. Or increases the foreign body reaction, 22 correct? 23 A. When you're talking about foreign body 24 reaction, I would expect to, to see in an ultrasound or 25 an MRI, with as good as a resolution as it is, I would</p>	<p>Page 320</p> <p>1 A. Yes. 2 Q. And have you ever participated as the 3 voice, as the customer in Ethicon meetings? 4 A. At some point they may have asked me and 5 that's the way they would write it down. 6 (Plaintiff's Exhibit No. 27 was marked 7 for identification.) 8 BY MR. FREESE: 9 Q. Let me show you Exhibit 27 to your 10 deposition, sir. You see this memo, VOC on New 11 Laser-Cut TVT Mesh? 12 A. Yes. 13 Q. And it's to Paul Parisi and Kevin Mahar, 14 do you see that? 15 A. Yes. 16 Q. Do you know those men? 17 A. Yes. 18 Q. It says here qualitative one on ones on 19 the topic the laser-cut mesh versus traditionally-cut 20 mesh were completed the weekend of December 10 and 11 21 with several preceptors: Dr. Vince Lucente, Dr. David 22 Robinson, Dr. Dennis Miller, Dr. Jim Raders, Dr. Bob 23 Rogers, Dr. Jaime Sepulveda, Dr. Chip Hanes, and Dr. 24 Aaron Kirkomo. 25 A. Yes.</p>
<p>Page 319</p> <p>1 like to see any reaction from a particle loss. 2 Q. I understand you'd like to, but my 3 question is a little more simple. You don't have any 4 opinions whether or not particle loss on TVTO or any 5 midurethral sling is ever clinically significant, 6 correct? 7 A. I don't have an opinion on clinical 8 significant. Actually, I don't think it has been 9 quantified. That's why I can't offer an opinion. 10 Q. And you've never seen any study by 11 Ethicon trying to determine whether or not particle 12 loss has any clinical significance, correct? 13 A. I'm not aware of any study correlating 14 particle loss or foreign body reaction from the 15 particle loss to the final outcome of a sling. 16 Q. Okay. And if there was a clinical 17 significance to particle loss, you'd want to know about 18 it, would you not? 19 A. I would like to learn about it. 20 Q. Doctor, do you remember meetings, Voice 21 of Customer meetings at Ethicon? 22 A. That's a marketing term, Voice of 23 Customers. 24 Q. You know what VOC means, Voice of 25 Customers?</p>	<p>Page 321</p> <p>1 Q. Do you recall this meeting? 2 A. No. 3 Q. Okay. Laser-cut mesh was introduced in 4 2006, is that right? 5 A. I don't know. 6 Q. Do you know Allison London Brown? 7 A. I met Allison, yes. 8 Q. Okay. And who is she? 9 A. She, says here she is a program director. 10 She was, yes, program director then. 11 Q. Do you know Paul Parisi? 12 A. Yes. 13 Q. Who is he? 14 A. He was I believe a liaison with 15 physicians. 16 Q. And Kevin Mahar, who is he? 17 A. Kevin may have been a salesperson. 18 Q. All right. Do you see on the second page 19 it says, quote, "denaturing/linting"? 20 A. Yes. 21 Q. Only four of the doctors to whom I spoke 22 had previous personal issues with linting factor, but 23 all expressed concern with it on behalf of other 24 colleagues who may have experienced negative problems 25 with it. Dr. Rogers made note that some peers may</p>

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<p>1 replace the first mesh if linting occurs, as they are      2 concerned with leaving particles in their patient. Dr.      3 Sepulveda said he had noticed the linting in patients      4 after their next-day adjustment. All noted with some      5 prompting that this was definitely a needed      6 improvement. Do you see that?</p> <p>7 A. Yeah, I don't know what she means by      8 next-day adjustment or linting.</p> <p>9 Q. Well, you were quoted by Allison London      10 Brown as saying that you had noticed linting in      11 patients. Do you see that?</p> <p>12 A. Not only did Allison London Brown quoted      13 me on next-day adjustment, which I have never, I don't      14 know what next-day adjustment is, she spelled my name      15 wrong, too.</p> <p>16 Q. Okay. So, you don't deny being at this      17 meeting?</p> <p>18 A. I don't even know if I was at this      19 meeting. I can tell you that this, this is not, I      20 cannot remember and this is inaccurate.</p> <p>21 Q. All right. It says denaturing and      22 linting, correct?</p> <p>23 A. I don't ever remember -- I don't use the      24 term linting.</p> <p>25 Q. Sir, the document says denaturing and</p>	<p>1 A. And I don't recall --</p> <p>2 Q. I understand that, Doctor. Listen to my      3 question. According to Allison London Brown, in a      4 meeting you were at, Dr. Rogers was equating linting      5 with particle loss, correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay, and she reports that you had      8 noticed this linting in your patients, correct?</p> <p>9 A. She records that I have seen linting.</p> <p>10 Q. And says at the next-day adjustment, and      11 you say that just never happened, you never reported      12 this to Allison London Brown?</p> <p>13 A. I don't use linting as a word.</p> <p>14 Q. Sir, I'm just asking you, you never      15 reported to Allison London Brown that you had seen      16 particle loss in patients after their next-day      17 adjustment?</p> <p>18 A. I do not recall reporting this to Allison      19 London Brown.</p> <p>20 Q. Did she just make this up or lie or what?</p> <p>21 MR. WALKER: Objection.</p> <p>22 A. I don't even know what she did. I just      23 tell you what I can tell you, that I don't recall ever      24 mentioning this to her.</p> <p>25 BY MR. FREESE:</p>
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<p>1 linting, does it not?</p> <p>2 A. Right.</p> <p>3 Q. And it says Dr. Sepulveda said that he      4 had noticed the linting in patients. First of all, had      5 you ever noticed particle loss in patients?</p> <p>6 A. I had seen one or two particles, yes, but      7 it doesn't make a difference in my sling.</p> <p>8 Q. I'm just asking, have you seen particle      9 loss before?</p> <p>10 A. Yes, I have seen particle loss before.</p> <p>11 Q. Is that a wanted or unwanted event when      12 you're placing a synthetic sling?</p> <p>13 MR. WALKER: Objection.</p> <p>14 A. That is a, that is an event that we used      15 to recognize as part of the open weave meshes.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. Now, you can tell from the context here      18 that denaturing and linting is synonymous with leaving      19 particles in the patient, correct? That's what it      20 says?</p> <p>21 A. No, I can not conclude this from that.</p> <p>22 Q. It says Dr. Rogers made note that some      23 peers may replace the first mesh if linting occurs,      24 comma, as they are concerned with leaving particles in      25 the patient. Do you see that?</p>	<p>1 Q. She says all, so that would include you,      2 right? All noted with some prompting that this was      3 definitely a needed improvement. Do you see that?</p> <p>4 MR. WALKER: Object to form.</p> <p>5 A. Yes, I see that she writes that.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Do you agree that laser-cut mesh either      8 solved or substantially improved the particle loss      9 problem with mechanically-cut TVT mesh?</p> <p>10 MR. WALKER: Object to form.</p> <p>11 A. No, I think that they are two different      12 products for the sling, but we recognize that as      13 surgeons.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. But my question is, Doctor, is, do you      16 agree that after the introduction of laser-cut mesh,      17 that it lessened particle loss that was seen with      18 mechanically-cut mesh?</p> <p>19 A. Laser-cut mesh have less particle loss      20 than mechanically-cut mesh.</p> <p>21 Q. And you knew it at the time that it was      22 introduced, correct?</p> <p>23 A. I, basically I saw that laser-cut mesh      24 was a next generation of it.</p> <p>25 Q. And, in fact, you participated as a voice</p>

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<p>1 of the customer for Ethicon, did you not?</p> <p>2 A. Well, that's what it says in this</p> <p>3 document.</p> <p>4 MR. WALKER: Object to form.</p> <p>5 A. I already told you I don't recall this.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Well, it says methodology included blind</p> <p>8 introduction of new material for panelists, initial</p> <p>9 reaction and follow-up questioning to understand</p> <p>10 overall acceptance of the new material, elasticity,</p> <p>11 memory, denaturing and linting. Do you see that?</p> <p>12 A. Yeah, let me, let me read, let me read</p> <p>13 this, because there's no date on this.</p> <p>14 Q. You know who has a date, don't you?</p> <p>15 A. No.</p> <p>16 Q. This guy right here. He can tell us a</p> <p>17 date. He can probably tell us right now from his</p> <p>18 laptop. I don't have a date, I'm just messing with</p> <p>19 you. I'd give you a date if I had it, but it appears</p> <p>20 to be in the year that laser cut was introduced. But</p> <p>21 you're welcome to look at the document.</p> <p>22 A. I don't recall this thing, but to the</p> <p>23 best of my ability, and I'm obviously under oath, I</p> <p>24 don't recall this thing.</p> <p>25 Q. But you don't dispute that it happened</p>	<p>1 do see that.</p> <p>2 Q. Okay. But that really wasn't my</p> <p>3 question, so that didn't really respond to anything,</p> <p>4 I'll move to strike that.</p> <p>5 But my question was in the memory section</p> <p>6 of that document, does that refresh what your view was</p> <p>7 of the laser-cut mesh whenever this meeting occurred?</p> <p>8 A. I don't recall this meeting in detail.</p> <p>9 This is, if someone would have tested on me, I would</p> <p>10 have failed that test.</p> <p>11 MR. FREESE: I think that's all I got.</p> <p>12 I've got a lot more, but that's all for today.</p> <p>13 (Witness was excused at 5:10 p.m.)</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 and that there was a contemporaneous record of this</p> <p>2 meeting made, you don't dispute that?</p> <p>3 A. Well, there was a record, I just don't</p> <p>4 know when this was, I don't recall using the term</p> <p>5 linting, and it's just not something that I use on my,</p> <p>6 on the time that I was with them.</p> <p>7 Q. Last question. You see where it says</p> <p>8 memory, without prompting, several subject, paren,</p> <p>9 Lucente, Sepulveda, Rogers, Raders, Robinson, noted</p> <p>10 that the new material rebounded or bounced back and</p> <p>11 that this seemed unique over previous materials used,</p> <p>12 TVT or competition. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Does that accurately describe your view</p> <p>15 of laser-cut mesh versus mechanically-cut mesh in TTVT?</p> <p>16 A. I think that this is, this may have been</p> <p>17 one of those meetings in which they would give you one</p> <p>18 product and they would have you say what you feel with</p> <p>19 it, and, really, it's not a, there's not much science</p> <p>20 in it. Now, did I see particle loss? I think the</p> <p>21 essence of your question is, did I see particle loss</p> <p>22 that would make me shy away or stop using non-laser-cut</p> <p>23 mesh? No, most of the data on TTVT and TVTO that I'm</p> <p>24 aware of is using non-laser-cut mesh. Do I see</p> <p>25 laser-cut mesh as the next generation of mesh? Yes, I</p>	<p>1 STATE OF FLORIDA.)</p> <p>2 COUNTY OF PALM BEACH.)</p> <p>3</p> <p>4 I, the undersigned authority, certify that</p> <p>5 JAIME SEPULVEDA, M.D., personally appeared before me on</p> <p>6 April 8, 2016, and was duly sworn.</p> <p>7</p> <p>8 WITNESS my hand and official seal this 11th</p> <p>9 day of April, 2016.</p> <p>10</p> <p>11</p> <p>12</p> <p>13 Dorothy Linda Minor, RPR</p> <p>14</p> <p>15 DOROTHY LINDA MINOR</p> <p>16 MY COMMISSION # EE 187711</p> <p>17 EXPIRES: August 8, 2016</p> <p>18 Bonded Thru Budget Notary</p> <p>19 Services</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p style="text-align: center;">Page 330</p> <p>1 THE STATE OF FLORIDA,)    2 COUNTY OF PALM BEACH.)    3 I, Dorothy Linda Minor, Registered    4 Professional Reporter, certify that I was authorized to    5 and did stenographically report the deposition of JAIME    6 SEPULVEDA, M.D.; that a review of the transcript was    7 not requested; and that pages 7 through 328, inclusive,    8 are a true and complete record of my stenographic    9 notes.    10 I further certify that I am not a relative,    11 employee, attorney or counsel of any of the parties,    12 nor am I a relative or employee of any of the parties'    13 attorneys or counsel connected with the action, nor am    14 I financially interested in the action.    15 DATED this 11th day of April, 2016.    16    17    18 _____    19 Dorothy Linda Minor, RPR    20    21    22    23    24    25</p>	<p style="text-align: center;">Page 332</p> <p>1 ACKNOWLEDGMENT OF DEPONENT    2 I, JAIME SEPULVEDA, M.D., do hereby    3 certify that I have read the foregoing pages, and that    4 the same is a correct transcription of the answers    5 given by me to the questions therein propounded, except    6 for the corrections or changes in form or substance, if    7 any, noted in the attached Errata Sheet.    8    9    10 _____    11 JAIME SEPULVEDA, M.D. DATE    12    13    14 Subscribed and sworn    to before me this    15 _____ day of _____, 20___.    16 My commission expires: _____    17    Notary Public    18    19    20    21    22    23    24    25</p>
<p style="text-align: center;">Page 331</p> <p>1 -----    2 -----    3 ERRATA    4 -----    5 PAGE LINE CHANGE    6 -----    7 REASON: _____    8 -----    9 REASON: _____    10 -----    11 REASON: _____    12 -----    13 REASON: _____    14 -----    15 REASON: _____    16 -----    17 REASON: _____    18 -----    19 REASON: _____    20 -----    21 REASON: _____    22 -----    23 REASON: _____    24    25</p>	

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